

foiapa

18-04383-E

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, May 18, 2018 8:24 PM
To: foiapa
Subject: FOIA Request

RECEIVED

MAY 21 2018

Office of
FOIA Services

would like to request access to Exhibit 10.20 to the 3/31/06 10-Q, filed by Foxhollow Technologies, Inc. on 5/9/2006. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

June 20, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04383-E

Dear Mr. Edwards:

This letter is in response to your request, dated and received in this office on May 21, 2018, for information regarding Exhibit 10.20 to the Form 10-Q, filed by Foxhollow Technologies, Inc. on May 9, 2006.

The search for responsive records has resulted in the retrieval of 29 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at smithLR@sec.gov or (202) 551-8328. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Smith".

La Kisha R. Smith
FOIA Research Specialist

Enclosure

Confidential Treatment Requested
Under 17 C.F.R. §§ 200.80(b)(4)
and 240.24b-2

FoxHollow Technologies, Inc.

Exhibit 10.20

MARKED, UNREDACTED VERSION

(FoxHollow Technologies, Inc. requests confidential treatment for the highlighted material)

ORIGINAL EQUIPMENT MANUFACTURING AGREEMENT

BETWEEN COOK INCORPORATED & FOXHOLLOW TECHNOLOGIES, INC.

This Original Equipment Manufacturing Agreement ("**Agreement**") is effective as of the 4th day of May, 2006 ("**Effective Date**") by and between Cook Incorporated and ("**Cook**"), an Indiana corporation, with offices located at 750 Daniels Way, Bloomington Indiana, 46404, and FoxHollow Technologies, Inc. ("**FTI**"), a Delaware corporation with its principal place of business at 740 Bay Road, Redwood City, California, 94063.

Preliminary Statements

1. Cook is engaged in the manufacture of certain medical devices including a FLEXOR® Sheath 7 French and 8 French Raabe (the "**Product**");
2. FTI is engaged in the sale and marketing of medical devices;
3. Cook is willing and able to manufacture the Product to specifications approved by both FTI and Cook, and to sell the Product to FTI on the terms and conditions set forth herein; and
4. FTI desires to have Cook act as an original equipment manufacturer for the Product.

In consideration of the promises hereof, and the mutual obligations herein made and undertaken and for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

Agreement

1. Term of the Agreement.

(a) This Agreement shall commence on the Effective Date and shall continue for an initial period which shall expire on December 31, 2007 unless sooner terminated as provided herein (the "**Initial Term**").

(b) Cook may elect to renew this Agreement for successive one (1) year periods (each a "**Renewal Period**") by giving written notice to FTI sixty (60) days prior to the expiration of the Initial Term or the then current Renewal Period, as the case may be, unless FTI sends notice to Cook of FTI's intent not to renew this Agreement at least thirty (30) days prior to the expiration of the then current term.

(c) The "**Term**" of this Agreement means the Initial Term and any Renewal Period(s) of this Agreement as provided under Sections 1(a) and (b) above.

2. Manufacturing and Labeling.

- 2.1. Specifications. Cook shall manufacture and deliver the sterile Product meeting the specifications set forth on Exhibit A, as attached hereto (the "**Specifications**").
- 2.2. Packaging and Labeling. The Product shall be initially packaged and labeled by Cook. Such packaging and labeling shall meet the requirements set forth on Exhibit B, as attached hereto.

3. Product Price.

- 3.1. Product Purchase Price. The price to be paid by FTI for the Product ("**Purchase Price**") shall be set forth in Exhibit C attached hereto and by reference made a part hereof. FTI will not sell, dispose of or otherwise transfer any units of Product for an amount less than the Purchase Price for such unit of Product.
- 3.2. Purchase Price Adjustment. Upon the first anniversary of the date of this Agreement and on each anniversary thereafter, the Purchase Price of such Product may be adjusted to reflect changes in the cost of materials provided by Cook and wages paid by Cook in connection with the manufacture of such Product. Cook shall provide FTI with written notice setting forth the amount of such Purchase Price increase.

4. Orders and Capacity Terms.

- 4.1. Forecasts. On the first day of each month during the Term, FTI shall provide Cook with a rolling forecast of estimated purchases of the Product for the following three months.
- 4.2. Purchase Orders. No later than six (6) weeks prior to a required delivery for the Product, FTI shall provide Cook with a purchase order for FTI's requirements of the Product to be purchased from Cook pursuant to this Agreement ("**Purchase Orders**"). All Purchase Orders shall be for a minimum of one thousand (1,000) units of the Product. Provided that such quantities were forecasted, Cook shall make all reasonable efforts to deliver the Product in accordance with the Purchase Order or in accordance with any reasonably requested timetable that is agreed to by Cook. Cook reserves the right to modify any agreed delivery terms, so long as such modifications are not unreasonable under the circumstances. Subject to the foregoing, FTI may not cancel or modify a Purchase Order without Cook's written consent.
- 4.3. Conflict in Terms. To the extent any of FTI's order-related documents or any of Cook's sales-related instruments (including, but not limited to its acknowledgment, invoice or similar forms) contain any terms or conditions which are inconsistent with this Agreement, this Agreement shall govern.

5. Shipment and Invoicing.

- 5.1. Delivery Terms. Product shall be delivered to FTI, or to a location designated by FTI in the Purchase Order, from Cook's facility in Bloomington, Indiana at FTI's expense by a common carrier designated by FTI; provided, however, Cook shall be responsible for the loading of the Product on departure and shall bear risk of loss and all costs of such loading. FTI shall procure, at its cost, insurance covering damage or loss to the Product during shipping.
- 5.2. Export. Purchaser will be the exporter of record for any Product shipped outside of the United States. FTI warrants that all shipments of the Product outside of the United States will be made in compliance with all applicable United States export laws and regulations, including the Export Administration Act, and all applicable import laws and regulations.
- 5.3. Payment Terms. FTI shall pay for the Product in U.S. Dollars and payment shall be made in full to Cook at the address first written above. FTI shall make payment net thirty (30) days from the date of shipment. FTI shall not be entitled to offset or deduct any amount from the invoice.
- 5.4. Default in Payment Obligations. In addition to all other remedies available to Cook in the event of a FTI default, if FTI fails to make payments as required hereunder, Cook shall notify FTI in writing of its default and FTI shall be entitled to a 10-day grace period beginning on the date that FTI receives the notice of default. After such 10-day grace period, Cook may refuse all further Purchase Orders, refuse to manufacture the Product until FTI's account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of the Product until FTI provides assurance of performance reasonably satisfactory to Cook, and/or take other reasonable means as Cook may determine.

6. Acceptance.

FTI may only return the Products to Cook if the Products fail to meet the Specifications. FTI, at its own option, will inspect and examine the Product within fourteen (14) days of delivery at FTI's facility. If FTI, upon examination of the Product, becomes aware of any defect in the Product, FTI shall notify Cook within fourteen (14) business days of detection of such defect in the Product. If, and to the extent FTI fails to examine the delivery of the Product or fails to notify Cook, the Product shall be deemed to have been accepted by FTI in satisfactory condition and as meeting the Specifications.

7. Compliance with Laws and Regulations.

7.1. Cook Obligations.

- 7.1.1. Cook will, at its own expense, obtain, maintain and comply with any and all applicable approvals, governmental or other permits, and all other administrative, regulatory and legal requirements necessary to fulfill its

obligations to FTI under this Agreement, including, but not limited to, the manufacturing, packaging, sterilization, labeling and distribution of the Product for and to FTI.

- 7.1.2. If Cook receives from a third party or any regulator any oral or written complaint regarding the Product, it will promptly notify FTI of such complaint in writing, in reasonable detail, but no later than five (5) business days after its receipt of such complaint, and will provide all information necessary to enable FTI to comply with applicable government or other regulatory requirements, and any other applicable legal requirements, in a timely fashion.
- 7.1.3. Cook is responsible for providing the necessary and appropriate labeling and instructions for use of the Product in the markets in which FTI sells the Product. FTI will use its best efforts to ensure that the Products are used in accordance with such labeling and instructions by way of correct handling provisions concerning the Product and corresponding instructions delivered to FTI's customers.
- 7.1.4. Cook will be responsible for investigating complaints under applicable law and filing any required medical device reporting, with the appropriate government agencies in accordance with applicable law. To the extent necessary to comply with regulatory requirements, FTI will provide to Cook, and update in a timely manner during the Term of this Agreement, a complete list of customers that purchase the Product.

7.2. FTI Obligations.

- 7.2.1. FTI will, at its own expense, obtain, maintain and comply with all approvals, governmental permits or other administrative law requirements necessary for the resale and distribution, in the markets in which FTI sells the Product.
- 7.2.2. If FTI receives from a third party any oral or written complaint regarding the Product, it will promptly notify Cook of such complaint in writing, in reasonable detail, but no later than five (5) business days after its receipt of such complaint, and will provide all information necessary to enable Cook to comply with applicable government or other regulatory requirements, and any other applicable legal requirements, in a timely fashion.

8. Warranty.

Cook warrants that the Products supplied by Cook shall comply with the Specifications. COOK GIVES NO OTHER WARRANTY, EXPRESS OR IMPLIED, IN RESPECT OF THE QUALITY OF THE PRODUCT AND, IN PARTICULAR, GIVES NO WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE.

9. Liability.

- 9.1. Exclusive Remedy. Except as set forth in Section 10.2, Cook's entire liability and FTI's exclusive remedy for any breach of this Agreement or the warranty contained in Section 8 shall be limited to replacement of the non-conforming or defective Product. In addition, Cook shall dispose of, at its expense, any quantity of non-conforming Product supplied by Cook.
- 9.2. Consequential and Special Damages. IN NO EVENT SHALL COOK BE LIABLE FOR ANY CONSEQUENTIAL, CONTINGENT, SPECIAL OR INCIDENTAL DAMAGES, LOSSES OR EXPENSES WHATSOEVER WHICH MAY ARISE AS A RESULT OF THIS AGREEMENT OR OTHERWISE, OR ANY OTHER MATTER WITH RESPECT TO THE PRODUCTS, WHETHER USED ALONE OR IN COMBINATION WITH OTHER GOODS OR MATERIALS.

10. Indemnification.

- 10.1. FTI Indemnification. FTI shall indemnify, defend and hold harmless Cook and its directors, officers, employees, subcontractors and agents from and against any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees) arising out of or in connection with property damage or personal injury (including, without limitation, death) of third parties (collectively "**Claims**"), in connection with (a) FTI's storage, promotion, marketing, distribution, use or sale of the Product, (b) FTI's negligence or willful misconduct, or (c) FTI's breach of this Agreement, except to the extent any of the foregoing is caused by the negligence or willful misconduct of Cook or by the breach of Cook of its obligations under this Agreement.
- 10.2. Cook Indemnification. Cook shall indemnify, defend and hold harmless FTI and its directors, officers, employees, subcontractors and agents from and against any and all Claims to the extent arising or resulting from Cook negligence, including all claims arising from the design and manufacture of Product, or willful misconduct or from Cook's breach of its obligations under this Agreement.
- 10.3. Indemnatee Obligations. A party (the "**Indemnatee**") which intends to claim indemnification under this Section 10 shall promptly notify the other party (the "**Indemnitor**") in writing of any matter in respect of which the Indemnatee intends to claim such indemnification. Failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitor, at its discretion, may settle any such action, claim or other matter, and the Indemnatee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the Indemnatee's rights hereunder, or

impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. The Indemnitee and its respective directors, officers, employees, subcontractors and agents shall fully cooperate with the Indemnitor in the investigation and defense of any matter covered by the indemnification obligations of this Section 10. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

11. Recall of Product.

In the event FTI shall be required to recall any Product, or FTI product incorporating any Product because such Product may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Specifications, or in the event that FTI elects to institute a voluntary recall, FTI shall be responsible for coordinating such recall. Cook shall cooperate with FTI in connection with any recall, at Cook's expense. FTI shall be responsible for all costs and expenses of such recall except as follows: in the event a recall, product withdrawal or field correction is necessary because Cook has delivered a non-conforming Product to FTI, Cook will bear all reasonable costs associated with such recall, product withdrawal or field correction. For purposes of this Agreement, non-conforming means any Product that does not conform to the Specifications as set forth in Exhibit A.

12. Termination.

12.1. In addition to the parties' rights to terminate this Agreement as otherwise provided herein, either party may terminate this Agreement upon occurrence of any of the following events:

12.1.1. In the event of the other party's insolvency or its inability to pay debts as they become due, or the filing of a voluntary or involuntary bankruptcy proceeding by or against the other party, or the appointment of a receiver or assignee for the benefit of a party's creditors.

12.1.2. If the other party fails to perform any of its material obligations hereunder, the other party may terminate this Agreement unless such breach is cured within thirty (30) days, unless otherwise specified herein, following written notice of such default from the terminating party. Upon any default, the terminating party may pursue any and all of its rights and remedies hereunder at law and in equity.

13. Confidential Information, Nondisclosure and Publicity.

13.1. Confidentiality. Any process know-how or other valuable information proprietary to either party which is disclosed by that party to the other party in connection with this Agreement (whether such disclosure is oral, in writing or obtained by observation of the other party during a site visit or inspection) shall remain the property of the party making the disclosure and shall not, without the prior written consent of that party, be disclosed to any third party or used by the other party

except for the performance of that other party's obligations under this Agreement. ("**Confidential Information**"). The obligations of non-use and confidentiality contained in this Section 13 shall not apply to any information which (i) was already in the possession of the recipient or in the public domain prior to its disclosure by the other party, (ii) is purchased or otherwise legally acquired by the recipient at any time from a third party having good title thereto, or (iii) comes into the public domain, otherwise than through the fault of the recipient or is disclosed under compulsion of law to any court or government or regulatory authority.

13.2. Litigation and Governmental Disclosure.

13.2.1. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or to obtain patents with respect to the Product.

13.2.2. Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

13.3. Duration of Confidentiality. All documents supplied by either party to this Agreement to the other party which contain information within the scope of this Section 13 shall be promptly returned by the recipient to the party which supplied them upon the expiration or earlier termination of this Agreement and the obligations of each party under this Section 13 shall survive such expiration or termination.

14. Intellectual Property.

14.1. Confidentiality of Intellectual Property. Any idea, invention, trade secret, process, program, data, formula, patent, copyright, or trademark ("**Intellectual Property**") shall be deemed to be the Confidential Information of the party owning such Intellectual Property. Any disclosure of information by one party to the other under the provisions of this Section 14 shall be treated as the disclosure of a party's Confidential Information under this Agreement. It shall be the responsibility of the party preparing a patent application to obtain the written permission of the other party to use or disclose the other party's Confidential

Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

- 14.2. Existing Intellectual Property. Except as the parties may otherwise expressly agree in writing, each party shall continue to own its existing Intellectual Property without conferring any interests therein on the other party. Without limiting the generality of the preceding sentence, Cook shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all of the Product and trademarks associated therewith (collectively, "***Cook's Intellectual Property***"). Neither FTI nor any third party shall acquire any right, title or interest in Cook's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein. Likewise, without limiting the generality of the preceding sentences, FTI shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all products and trademarks associated therewith (collectively, "***FTI's Intellectual Property***"). Neither Cook nor any third party shall acquire any right, title or interest in FTI's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.
- 14.3. Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (a) a grant, transfer or other conveyance by either party to the other of any right, title, license or other interest of any kind in any of its inventions or other Intellectual Property, (b) creating an obligation on the part of either party to make any such grant, transfer or other conveyance, or (c) requiring either party to participate with the other party in any cooperative development program or project of any kind or to continue with any such program or project.
- 14.4. Publicity. Any literature, advertisement, publicity release or other material published by one party in connection with this Agreement that refers to the name of the other party must be pre-approved in writing by the other party.

15. General.

- 15.1. Governing Law. This Agreement shall be governed by the laws of the State of Indiana without regard to its choice of law provisions. Any claim or cause of action arising under this Agreement shall be filed in a court of competent jurisdiction within the state of Indiana.
- 15.2. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be illegal, invalid, or unenforceable, the remaining provisions of this Agreement shall not be affected or impaired thereby.
- 15.3. Non-Waiver. The failure of either party to enforce any term or condition of this Agreement shall not constitute (i) a waiver of such term or condition, (ii) to affect the validity of this Agreement, or (iii) to preclude or prejudice the party from exercising the same or any other rights it may have under the Agreement.
- 15.4. Successors and Assigns. The Agreement shall not be assignable by either party without the prior written consent of the other party. Any attempt to assign any part of this Agreement without such consent shall be void. Notwithstanding the foregoing, this Agreement may be assigned by and between Cook and its corporate parents, subsidiaries, and affiliates and by and between FTI and its corporate parents, subsidiaries, and affiliates. This Agreement shall be binding upon and inure to the benefit of the parties' future successors, and authorized assigns.
- 15.5. Notices. All notices required or provided under this Agreement shall be deemed effective when in writing and delivered to the party by a commercially recognized overnight courier, or by facsimile transmission if acknowledged by the recipient by return facsimile (or otherwise acknowledged in writing), to the addresses first written above. Addresses and facsimile numbers may be changed by the parties by giving notice of the new information pursuant to the terms of this Section 15.5.
- 15.6. Force Majeure. If performance of this Agreement or any obligation under this Agreement by the parties is hindered or prevented by an Act of God, action of the elements, fire, accident, war, or governmental restrictions or other such casualty or cause, beyond the control of the party required to perform and without such party's fault or negligence, performance by that party to the extent so hindered or prevented shall be exercised during the period of the force majeure condition. Within immediate discovery of a force majeure condition, the party whose performance is impeded by the force majeure shall notify promptly the other party of the existence of the force majeure and the anticipated duration thereof and shall be diligent in attempting to remove such force majeure condition.
- 15.7. Entire Agreement. Except as specified in Section 4.2 regarding purchase orders, this Agreement constitutes the entire Agreement between the parties with respect to its subject matter and supersedes all prior and contemporaneous agreements between the parties in connection with the same subject matter. This Agreement

may be amended, changed and modified only in writing executed by both parties hereto.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have set their hands and seals as of the 4th day of May, 2006 to this original equipment manufacturing agreement.

COOK INCORPORATED
("*Cook*")

FOXHOLLOW TECHNOLOGIES, INC.
("*FTI*")

By: /s/ Brian Bates

By /s/ Matthew B. Ferguson

Title: Sr. V.P. of Business Development

Title: CFO

Date: 5/4/06

Date: 5/4/06

EXHIBIT A

PRODUCT SPECIFICATIONS

The guiding sheaths provided by Cook under this Agreement consist of a coil reinforced sheath, hemostasis valve with side arm tubing, and a 0.038" compatible introduction dilator. The coil reinforced sheath material is constructed of an inner PTFE liner, stainless steel reinforcement coil, and an outer nylon jacket. The sheath material also has a radiopaque band at the distal tip. The configurations provided under this Agreement include the following:

Cook P/N	Description	I.D. (minimum)	O.D. (reference)
KCFW-7.0-38-55-RB-FH	7.0 French, 55cm Guiding Sheath	0.100"	0.124"
KCFW-8.0-38-55-RB-FH	8.0 French, 55cm Guiding Sheath	0.113"	0.137"

The product is packaged in standard pouches, sterile, and labeled according to mutually agreed upon specifications.

EXHIBIT B

PACKAGING AND LABELING

Product shall be labeled with the FTI label as described in this Exhibit B, and include "Manufactured by Cook."

7.0FR ACCEPTS DEVICES UP TO 7.0 FRENCH	
FH GUIDING SHEATH	
	
REF <input type="text"/>	GXXXX
KCFW-7.0-38-55-RB-FH	
LOT <input type="text"/>	1234567
 2008-xx	Rx only
 2005-xx	  
	STERILE EO
<div>Distributed by: FoxHollow 740 Bay Road Redwood City, CA</div> <div>KCFW-7.0-38-55-RB-FH  (01)0082700236282x(17)xxxxxx(10)xxxxxx</div>	
Manufactured by Cook Incorporated	

BL1

EXHIBIT C
PURCHASE PRICE

1. (a) For units one (1) through seven thousand five hundred (7,500) purchased during the Initial Term, and thereafter during each Renewal Period, the purchase price is fifty-eight dollars (\$58.00) per unit.

(b) for units seven thousand five hundred and one (7501) through fifteen thousand (15,000) purchased during the Initial Term, and thereafter during each Renewal Period, the purchase price is decreased to fifty-six dollars (\$56.00) per unit.

(c) If the units purchased during the Initial Term, and thereafter during each Renewal Period, exceed fifteen thousand (15,000), then the purchase price is decreased to fifty four dollars (\$54.00) per unit for the units purchased above fifteen thousand (15,000).

**Confidential Treatment Requested
Under 17 C.F.R. §§ 200.80(b)(4)
and 240.24b-2**

FoxHollow Technologies, Inc.

Exhibit 10.20

REDACTED VERSION

EX-10.20 2 dex1020.htm ORIGINAL EQUIPMENT MANUFACTURING AGREEMENT

Exhibit 10.20

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Preliminary Statements

1. Cook is engaged in the manufacture of certain medical devices including [***] (the "**Product**");
2. FTI is engaged in the sale and marketing of medical devices;
3. Cook is willing and able to manufacture the Product to specifications approved by both FTI and Cook, and to sell the Product to FTI on the terms and conditions set forth herein; and
4. FTI desires to have Cook act as an original equipment manufacturer for the Product.

In consideration of the promises hereof, and the mutual obligations herein made and undertaken and for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

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*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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- 4.1. Forecasts. On the first day of each month during the Term, FTI shall provide Cook with a rolling forecast of estimated purchases of the Product for the following three months.
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5. Shipment and Invoicing.

- 5.1. Delivery Terms. Product shall be delivered to FTI, or to a location designated by FTI in the Purchase Order, from Cook's facility in Bloomington, Indiana at FTI's expense by a common carrier designated by FTI; provided, however, Cook shall be responsible for the loading of the Product on departure and shall bear risk of loss and all costs of such loading. FTI shall procure, at its cost, insurance covering damage or loss to the Product during shipping.
- 5.2. Export. Purchaser will be the exporter of record for any Product shipped outside of the United States. FTI warrants that all shipments of the Product outside of the United States will be made in compliance with all applicable United States export laws and regulations, including the Export Administration Act, and all applicable import laws and regulations.
- 5.3. Payment Terms. FTI shall pay for the Product in U.S. Dollars and payment shall be made in full to Cook at the address first written above. FTI shall make payment net thirty (30) days from the date of shipment. FTI shall not be entitled to offset or deduct any amount from the invoice.
- 5.4. Default in Payment Obligations. In addition to all other remedies available to Cook in the event of a FTI default, if FTI fails to make payments as required hereunder, Cook shall notify FTI in writing of its default and FTI shall be entitled to a 10-day grace period beginning on the date that FTI receives the notice of default. After such 10-day grace period, Cook may refuse all further Purchase Orders, refuse to manufacture the Product until FTI's account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of the Product until FTI provides assurance of performance reasonably satisfactory to Cook, and/or take other reasonable means as Cook may determine.

6. Acceptance.

FTI may only return the Products to Cook if the Products fail to meet the Specifications. FTI, at its own option, will inspect and examine the Product within fourteen (14) days of delivery at FTI's facility. If FTI, upon examination of the Product, becomes aware of any defect in the Product, FTI shall notify Cook within fourteen (14) business days of detection of such defect in the Product. If, and to the extent FTI fails to examine the delivery of the Product or fails to notify Cook, the Product shall be deemed to have been accepted by FTI in satisfactory condition and as meeting the Specifications.

7. Compliance with Laws and Regulations.

7.1. Cook Obligations.

- 7.1.1. Cook will, at its own expense, obtain, maintain and comply with any and all applicable approvals, governmental or other permits, and all other administrative, regulatory and legal requirements necessary to fulfill its

obligations to FTI under this Agreement, including, but not limited to, the manufacturing, packaging, sterilization, labeling and distribution of the Product for and to FTI.

- 7.1.2. If Cook receives from a third party or any regulator any oral or written complaint regarding the Product, it will promptly notify FTI of such complaint in writing, in reasonable detail, but no later than five (5) business days after its receipt of such complaint, and will provide all information necessary to enable FTI to comply with applicable government or other regulatory requirements, and any other applicable legal requirements, in a timely fashion.
- 7.1.3. Cook is responsible for providing the necessary and appropriate labeling and instructions for use of the Product in the markets in which FTI sells the Product. FTI will use its best efforts to ensure that the Products are used in accordance with such labeling and instructions by way of correct handling provisions concerning the Product and corresponding instructions delivered to FTI's customers.
- 7.1.4. Cook will be responsible for investigating complaints under applicable law and filing any required medical device reporting, with the appropriate government agencies in accordance with applicable law. To the extent necessary to comply with regulatory requirements, FTI will provide to Cook, and update in a timely manner during the Term of this Agreement, a complete list of customers that purchase the Product.

7.2. FTI Obligations.

- 7.2.1. FTI will, at its own expense, obtain, maintain and comply with all approvals, governmental permits or other administrative law requirements necessary for the resale and distribution, in the markets in which FTI sells the Product.
- 7.2.2. If FTI receives from a third party any oral or written complaint regarding the Product, it will promptly notify Cook of such complaint in writing, in reasonable detail, but no later than five (5) business days after its receipt of such complaint, and will provide all information necessary to enable Cook to comply with applicable government or other regulatory requirements, and any other applicable legal requirements, in a timely fashion.

8. Warranty.

Cook warrants that the Products supplied by Cook shall comply with the Specifications. COOK GIVES NO OTHER WARRANTY, EXPRESS OR IMPLIED, IN RESPECT OF THE QUALITY OF THE PRODUCT AND, IN PARTICULAR, GIVES NO WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE.

9. Liability.

- 9.1. Exclusive Remedy. Except as set forth in Section 10.2, Cook's entire liability and FTI's exclusive remedy for any breach of this Agreement or the warranty contained in Section 8 shall be limited to replacement of the non-conforming or defective Product. In addition, Cook shall dispose of, at its expense, any quantity of non-conforming Product supplied by Cook.
- 9.2. Consequential and Special Damages. IN NO EVENT SHALL COOK BE LIABLE FOR ANY CONSEQUENTIAL, CONTINGENT, SPECIAL OR INCIDENTAL DAMAGES, LOSSES OR EXPENSES WHATSOEVER WHICH MAY ARISE AS A RESULT OF THIS AGREEMENT OR OTHERWISE, OR ANY OTHER MATTER WITH RESPECT TO THE PRODUCTS, WHETHER USED ALONE OR IN COMBINATION WITH OTHER GOODS OR MATERIALS.

10. Indemnification.

- 10.1. FTI Indemnification. FTI shall indemnify, defend and hold harmless Cook and its directors, officers, employees, subcontractors and agents from and against any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees) arising out of or in connection with property damage or personal injury (including, without limitation, death) of third parties (collectively "Claims"), in connection with (a) FTI's storage, promotion, marketing, distribution, use or sale of the Product, (b) FTI's negligence or willful misconduct, or (c) FTI's breach of this Agreement, except to the extent any of the foregoing is caused by the negligence or willful misconduct of Cook or by the breach of Cook of its obligations under this Agreement.
- 10.2. Cook Indemnification. Cook shall indemnify, defend and hold harmless FTI and its directors, officers, employees, subcontractors and agents from and against any and all Claims to the extent arising or resulting from Cook negligence, including all claims arising from the design and manufacture of Product, or willful misconduct or from Cook's breach of its obligations under this Agreement.
- 10.3. Indemnatee Obligations. A party (the "Indemnatee") which intends to claim indemnification under this Section 10 shall promptly notify the other party (the "Indemnitor") in writing of any matter in respect of which the Indemnatee intends to claim such indemnification. Failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitor, at its discretion, may settle any such action, claim or other matter, and the Indemnatee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the Indemnatee's rights hereunder, or

impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. The Indemnitee and its respective directors, officers, employees, subcontractors and agents shall fully cooperate with the Indemnitor in the investigation and defense of any matter covered by the indemnification obligations of this Section 10. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

11. Recall of Product.

In the event FTI shall be required to recall any Product, or FTI product incorporating any Product because such Product may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Specifications, or in the event that FTI elects to institute a voluntary recall, FTI shall be responsible for coordinating such recall. Cook shall cooperate with FTI in connection with any recall, at Cook's expense. FTI shall be responsible for all costs and expenses of such recall except as follows: in the event a recall, product withdrawal or field correction is necessary because Cook has delivered a non-conforming Product to FTI, Cook will bear all reasonable costs associated with such recall, product withdrawal or field correction. For purposes of this Agreement, non-conforming means any Product that does not conform to the Specifications as set forth in Exhibit A.

12. Termination.

12.1. In addition to the parties' rights to terminate this Agreement as otherwise provided herein, either party may terminate this Agreement upon occurrence of any of the following events:

12.1.1. In the event of the other party's insolvency or its inability to pay debts as they become due, or the filing of a voluntary or involuntary bankruptcy proceeding by or against the other party, or the appointment of a receiver or assignee for the benefit of a party's creditors.

12.1.2. If the other party fails to perform any of its material obligations hereunder, the other party may terminate this Agreement unless such breach is cured within thirty (30) days, unless otherwise specified herein, following written notice of such default from the terminating party. Upon any default, the terminating party may pursue any and all of its rights and remedies hereunder at law and in equity.

13. Confidential Information, Nondisclosure and Publicity.

13.1. Confidentiality. Any process know-how or other valuable information proprietary to either party which is disclosed by that party to the other party in connection with this Agreement (whether such disclosure is oral, in writing or obtained by observation of the other party during a site visit or inspection) shall remain the property of the party making the disclosure and shall not, without the prior written consent of that party, be disclosed to any third party or used by the other party

except for the performance of that other party's obligations under this Agreement. ("**Confidential Information**"). The obligations of non-use and confidentiality contained in this Section 13 shall not apply to any information which (i) was already in the possession of the recipient or in the public domain prior to its disclosure by the other party, (ii) is purchased or otherwise legally acquired by the recipient at any time from a third party having good title thereto, or (iii) comes into the public domain, otherwise than through the fault of the recipient or is disclosed under compulsion of law to any court or government or regulatory authority.

13.2. Litigation and Governmental Disclosure.

13.2.1. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or to obtain patents with respect to the Product.

13.2.2. Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

13.3. Duration of Confidentiality. All documents supplied by either party to this Agreement to the other party which contain information within the scope of this Section 13 shall be promptly returned by the recipient to the party which supplied them upon the expiration or earlier termination of this Agreement and the obligations of each party under this Section 13 shall survive such expiration or termination.

14. Intellectual Property.

14.1. **Confidentiality of Intellectual Property.** Any idea, invention, trade secret, process, program, data, formula, patent, copyright, or trademark ("**Intellectual Property**") shall be deemed to be the Confidential Information of the party owning such Intellectual Property. Any disclosure of information by one party to the other under the provisions of this Section 14 shall be treated as the disclosure of a party's Confidential Information under this Agreement. It shall be the responsibility of the party preparing a patent application to obtain the written permission of the other party to use or disclose the other party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

- 14.2. Existing Intellectual Property. Except as the parties may otherwise expressly agree in writing, each party shall continue to own its existing Intellectual Property without conferring any interests therein on the other party. Without limiting the generality of the preceding sentence, Cook shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all of the Product and trademarks associated therewith (collectively, "*Cook's Intellectual Property*"). Neither FTI nor any third party shall acquire any right, title or interest in Cook's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein. Likewise, without limiting the generality of the preceding sentences, FTI shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all products and trademarks associated therewith (collectively, "*FTI's Intellectual Property*"). Neither Cook nor any third party shall acquire any right, title or interest in FTI's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.
- 14.3. Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (a) a grant, transfer or other conveyance by either party to the other of any right, title, license or other interest of any kind in any of its inventions or other Intellectual Property, (b) creating an obligation on the part of either party to make any such grant, transfer or other conveyance, or (c) requiring either party to participate with the other party in any cooperative development program or project of any kind or to continue with any such program or project.
- 14.4. Publicity. Any literature, advertisement, publicity release or other material published by one party in connection with this Agreement that refers to the name of the other party must be pre-approved in writing by the other party.

15. General.

- 15.1. Governing Law. This Agreement shall be governed by the laws of the State of Indiana without regard to its choice of law provisions. Any claim or cause of action arising under this Agreement shall be filed in a court of competent jurisdiction within the state of Indiana.
- 15.2. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be illegal, invalid, or unenforceable, the remaining provisions of this Agreement shall not be affected or impaired thereby.
- 15.3. Non-Waiver. The failure of either party to enforce any term or condition of this Agreement shall not constitute (i) a waiver of such term or condition, (ii) to affect the validity of this Agreement, or (iii) to preclude or prejudice the party from exercising the same or any other rights it may have under the Agreement.
- 15.4. Successors and Assigns. The Agreement shall not be assignable by either party without the prior written consent of the other party. Any attempt to assign any part of this Agreement without such consent shall be void. Notwithstanding the foregoing, this Agreement may be assigned by and between Cook and its corporate parents, subsidiaries, and affiliates and by and between FTI and its corporate parents, subsidiaries, and affiliates. This Agreement shall be binding upon and inure to the benefit of the parties' future successors, and authorized assigns.
- 15.5. Notices. All notices required or provided under this Agreement shall be deemed effective when in writing and delivered to the party by a commercially recognized overnight courier, or by facsimile transmission if acknowledged by the recipient by return facsimile (or otherwise acknowledged in writing), to the addresses first written above. Addresses and facsimile numbers may be changed by the parties by giving notice of the new information pursuant to the terms of this Section 15.5.
- 15.6. Force Majeure. If performance of this Agreement or any obligation under this Agreement by the parties is hindered or prevented by an Act of God, action of the elements, fire, accident, war, or governmental restrictions or other such casualty or cause, beyond the control of the party required to perform and without such party's fault or negligence, performance by that party to the extent so hindered or prevented shall be exercised during the period of the force majeure condition. Within immediate discovery of a force majeure condition, the party whose performance is impeded by the force majeure shall notify promptly the other party of the existence of the force majeure and the anticipated duration thereof and shall be diligent in attempting to remove such force majeure condition.
- 15.7. Entire Agreement. Except as specified in Section 4.2 regarding purchase orders, this Agreement constitutes the entire Agreement between the parties with respect to its subject matter and supersedes all prior and contemporaneous agreements between the parties in connection with the same subject matter. This Agreement may be amended, changed and modified only in writing executed by both parties hereto.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have set their hands and seals as of the 4th day of May, 2006 to this original equipment manufacturing agreement.

COOK INCORPORATED
("Cook")

By: /s/ Brian Bates

Title: Sr. V.P. of Business Development

Date: 5/4/06

FOXHOLLOW TECHNOLOGIES, INC.
("FTI")

By: /s/ Matthew B. Ferguson

Title: CFO

Date: 5/4/06

EXHIBIT A
PRODUCT SPECIFICATIONS

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

PACKAGING AND LABELING

Product shall be labeled with the FTI label as described in this Exhibit B, and include "Manufactured by Cook."

[***]

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C
PURCHASE PRICE

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.