We forecast sales to determine requirements for our products and if our forecasts are incorrect, we may experience either shipment delays or increased costs.

Our subcontractors keep limited materials and components on hand. To help them manage their manufacturing operations and minimize inventory costs, we forecast anticipated product orders to predict our inventory needs up to six months in advance and enter into purchase orders on the basis of these forecasts. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand would increase and our suppliers may be unable to meet our demand. If we overestimate our requirements, our subcontractors will have excess inventory, and may transfer to us any increase in costs. If we underestimate our requirements, our subcontractors may have inadequate components and materials inventory, which could interrupt, delay or prevent delivery of our products to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered into non-competition agreements with many of our professional employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under applicable employment laws, we may be unable to enforce these agreements, in whole or in part, and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property. If we cannot demonstrate that harm would be caused to us, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

We may become subject to the requirements of the 1940 Act, which would limit our business operations and require us to spend significant resources to comply with such act.

Section 3(a)(1)(C) of the 1940 Act defines an investment company as any issuer that "is engaged or proposes to engage in the business of investing, reinvesting, owning, holding or trading in securities, and owns or proposes to acquire investment securities having a value exceeding 40% of the value of such issuer's total assets (exclusive of U.S. government securities and cash items)." As of December 31, 2017 and 2016, we held approximately 34.1% and 16.2%, respectively, of our total assets (excluding U.S. government securities and cash items) in investment securities. As of September 30, 2018, we held approximately 51.2% of our total assets (excluding U.S. government securities and cash items) in investment securities, which exceeds the threshold definition of an investment company. Rule 3a-2 under the 1940 Act provides temporary relief from the registration requirements of the 1940 Act to an issuer that, on a transient basis, is deemed to be an investment company. We first exceeded this 40% asset threshold in June 2018, marking the beginning of a one-year safe harbor period under Rule 3a-2. The transient investment company exemption may be relied upon for a period of up to one year by an issuer that can demonstrate a bona fide intent to be, as soon as is reasonably possible, engaged primarily in a business other than that of investing, reinvesting, owning, holding or trading in investment securities. Additionally, such exemption is available to a company no more than once every three years, and assuming no other exclusions were available to us, we would have to comply with the 40% asset threshold for at least three years after we ceased being an inadvertent investment company. This may limit our ability to make certain investments or enter into joint ventures that could otherwise have a positive impact on our earnings. We do not intend to engage primarily in the business of investing, reinvesting, owning, holding or trading in investment securities but rather intend to engage primarily in the business of producing and distributing medical aesthetics products and solutions, and intend to reduce our holdings of investment securities to less than 40% of our total assets (excluding U.S. government securities and cash items) as soon as reasonably practicable. In order to comply with the 40% asset threshold, our board of directors intends to adopt prior to the consummation of this offering an investment policy that restricts our ability to acquire investment securities above the threshold. Such investment policy will govern future investments to ensure we are not deemed an investment company.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification demonstrating that our proposed device is "substantially equivalent," as defined in the statute, to a previously cleared 510(k) device or a device that was in commercial distribution in the United States before May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, for which the FDA has not yet called for the submission of premarket approval applications.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, if the FDA requires additional information, clearance often takes far longer, and clearance is never assured. Although most 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. A manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite PMA(s).

Laser devices used for aesthetic procedures, such as hair removal, have generally qualified for clearance under 510(k) procedures.

The table below presents the specific FDA 510(k) clearances, dates and summary of cleared indications for our *BodyTite*, *Optimas*, *Votiva*, *Contoura*, *Triton* and *EmbraceRF* platforms.

Product Platform	Energy Source	Handpiece	FDA 510(k) Clearance and Cleared Indications
BodyTite	Radiofrequency (RF)	*BodyTite* 40W	K171593 (10/10/2017) The *BodyTite* product platform with the *BodyTite* 40W handpiece is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
		BodyTite 20W	K163190 (12/12/2016) The *BodyTite* product platform with the *BodyTite* 20W handpiece is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Product Platform	Energy Source	Handpiece	FDA 510(k) Clearance and Cleared Indications
		FaceTite	K151793 (02/19/2016) The *BodyTite* product platform with the *FaceTite* handpiece is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
		Fractora with 60 Pin Tip	K102461 (06/02/2011) The *BodyTite* product platform with the *Fractora* with a 60 pin tip handpiece is indicated for use in dermatological procedures requiring ablation and resurfacing of the skin.
		Fractora with 24 Pin Tip	K151273 (01/04/2016) The *BodyTite* product platform with the *Fractora* with a 24 pin tip handpiece is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
		Morpheus8	K180189 (06/01/2018) The *BodyTite* product platform with the *Morpheus8* handpiece is indicated for the use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
Optimas	RF	*Fractora* with 60 Pin Tip	K102461 (06/02/2011) The *Optimas* product platform with the *Fractora* with a 60 pin tip handpiece is indicated for use in dermatological procedures requiring ablation and resurfacing of the skin.
		Fractora with 24 Pin Tip	K151273 (01/04/2016) The *Optimas* product platform with the *Fractora* with a 24 pin tip handpiece is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
	RF	*Forma*	K172302 (12/08/2017) The *Optimas* product platform with the *Forma* handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

Product Platform	Energy Source	Handpiece	FDA 510(k) Clearance and Cleared Indications
	Intense Pulsed Light (IPL)	*Lumecca* 515 *Lumecca* 580	K123860 (04/02/2013) The *Optimas* product platform with the *Lumecca* 515 and *Lumecca* 580 handpieces are indicated for: • the treatment of benign pigmented epidermal lesions, including dyschrornia, hyperpigmentation, melasma, ephelides (freckles); and • the treatment of benign cutaneous vascular lesions, including port wine stains, facial truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikilodenna of civatte, superficial leg veins and venous malformations.
	Laser	*DiolazeXL*	K170738 (08/07/2017) The *Optimas* product platform with the *DiolazeXL* handpiece is indicated for hair removal and permanent hair reduction.
	Laser	*Vasculaze*	K173677 (02/23/2018) The *Optimas* product platform with the *Vasculaze* handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
Votiva	RF	*FractoraV*	K151273 (01/04/2016) The *Votiva* product platform with the *FractoraV* handpiece is indicated for the use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
		FormaV	K153568 (07/12/2016)* The *Votiva* product platform with the *FormaV* handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

Product Platform	Energy Source	Handpiece	FDA 510(k) Clearance and Cleared Indications
Contoura	RF	*BodyFX*	K131362 (10/08/2013) The *Contoura* product platform with the *BodyFX* handpiece is indicated for the treatment of: • relief of minor muscle aches and pains, muscle spasms, temporary improvement of blood circulation; and • temporary reduction in the appearance of cellulite.
		MiniFX	K160329 (08/19/2016) The *Contoura* product platform with the *MiniFX* handpiece is indicated for the treatment of: • relief of minor muscle aches and pain, muscle spasms, temporary improvement of local blood circulation; and • temporary reduction in the appearance of cellulite.
		Plus	K172302 (12/08/2017) The *Contoura* product platform with the *Plus* handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasms, and temporary improvement of local blood circulation.
Triton	Laser	*Triton Duo Light* *Triton Duo Dark*	K180719 (06/14/2018) The *Triton* product platform with the *Triton Duo Light* and *Triton Duo Dark* handpieces are indicated for hair removal and permanent hair reduction.
EmbraceRF	RF	*FaceTite*	K151793 (02/19/2016) The *EmbraceRF* product platform with the *FaceTite* handpiece is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
		Morpheus8	K180189 (06/01/2018) The *EmbraceRF* product platform with the *Morpheus8* handpiece is indicated for the use in dermatological and general surgical procedures for electrocoagulation and homeostasis.

* In addition to the 510(k) clearance, we also market the *FormaV* for use with the *Votiva* platform pursuant to a classification regulation for "genital vibrators for therapeutic use" under 21 C.F.R. 884.5960, which permits "electronically operated device[s] intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone)" to be marketed without a 510(k) clearance.

Premarket Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling, to demonstrate the safety and effectiveness of the device to the FDA's satisfaction.

No device that we have developed has required premarket approval, nor do we currently expect that any future device or indication will require premarket approval.

Pervasive and Continuing Regulation

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

- quality system regulations, or QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- clearance or approval of product modifications to 510(k)-cleared or PMA-approved devices that could affect safety or effectiveness;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses;
- advertising and promotion requirements;
- medical device reporting regulations, which require that manufacturers report to the FDA if their devices may have caused or contributed to deaths or serious injuries or malfunctioned in ways that would likely cause or contribute to deaths or serious injuries if the malfunctions were to recur;
- medical device correction and removal reporting regulations, which require the manufacturers to report to the FDA corrections and removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the devices.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

prior to the consummation of this offering, we cannot effect a change of control transaction without Guangzhou Sino-Israel Bio-Industry Investment Fund (LLP)'s prior written consent. Guangzhou Sino-Israel Bio-Industry Investment Fund (LLP) also has a liquidation preference in the event of any liquidation, dissolution or winding up of the Chinese joint venture, whereby it has the right to be paid out of assets legally available for distribution, before any other shareholder of the Chinese joint venture, an amount in cash equal to its contribution to the Chinese joint venture.

In addition, Wigmore Medical Limited, a non-controlling partner in our U.K. joint venture (Invasix UK Ltd.), had the right to convert its non-controlling equity interest in such joint venture into our ordinary shares prior to the consummation of our initial public offering. Such joint venture is governed by a memorandum of understanding dated March 4, 2014 which we treat as a binding commitment. The number of ordinary shares that Wigmore Medical Limited would have been entitled to receive was based on the product of Wigmore Medical Limited's share percentage in Invasix UK Ltd. multiplied by Invasix UK Ltd.'s sales as a percentage of our total sales. However, on August 30, 2018, Wigmore Medical Limited waived any and all rights, privileges and interests with regards to such conversion right. Following receipt of the waiver, the non-controlling interest in Invasix UK Ltd. was reclassified as a non-controlling interest.

Indemnification Agreements

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we intend to enter into separate indemnification agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by law and undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent such liabilities are not covered by insurance. See "Management — Exculpation, Indemnification and Insurance of Directors and Officers" for additional information.

Employment and Consulting Agreements

We have entered into employment or consulting agreements with all of our executive officers and key employees. These agreements contain standard provisions for a company in our industry regarding non-solicitation, confidentiality of information, non-competition and assignment of inventions. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment, which varies for each individual. The agreements are terminable by us at will, subject to prior notice, which varies for each individual.