



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

February 10, 2011

Linda B. Grable  
Chief Executive Officer  
Imaging Diagnostic Systems, Inc.  
5307 NW 35th Terrace  
Fort Lauderdale, Florida 33309

**Re: Imaging Diagnostic Systems, Inc.  
Registration Statement on Form S-1  
Amended February 1, 2010  
File No. 333-171327**

Dear Ms. Grable:

We have limited our review of your registration statement to those issues we have addressed in our comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. Where you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Fee Table

1. Tell us the authority on which you rely to adjust the amount of the fee previously paid. Note the last sentence of Rule 457(b).

Use of Proceeds, page 20

2. We note your revised disclosure on page 20 detailing the expected use of the proceeds to be generated from this offering. Please clarify the "clinical and regulatory expenses" for which you plan to spend \$100,000 of the proceeds from this offering given your statement on page 32 that the costs associated with a 510(k) application are approximately \$62,000 and your response to prior comment 3 that sales of stock under

your equity line agreement with Southland during 2010 provided you with the funds used “in paying the 510(k) costs.”

Description of Business, page 25

Overview, page 25

3. With respect to your response to prior comment 2:
  - Please file the consent of the consultant from whom you disclose that you learned that you “could alternatively submit a 510(k) application instead of a PMA application....” Also, with a view toward disclosure, please tell us specifically the date on which the consultant provided you this advice and why you believe you had no obligation to disclose this information previously.
  - Reconcile your disclosure on pages 16 and 31 that you believe there exists a substantial equivalent to your product that allows you to meet the requirements of a 510(k) submission with:
    - your disclosure on page 26 that the FDA had previously determined that there was no predicate device and accordingly classified your product as a Class III medical device; and
    - your disclosure on page 31 that “Manufacturers of Class III devices must apply to the FDA for pre-marketing approval (“PMA”) before marketing can begin.”
  - Clarify what you mean by the “recent regulatory changes with the FDA agency” that you believe allow you to meet the requirements for a 510(k) submission. Specifically:
    - describe the changes to which you refer and tell us when those changes occurred;
    - clarify whether those specific changes had the effect of permitting 510(k) applications for Class III medical devices; and
    - provide us citations to the specific regulations to which you refer in response to this comment.
  - Advise us of the basis for your conclusion disclosed in the last paragraph on page 31 that your device “utilizes technology with low or moderate risk” such that a de novo 510(k) application would be appropriate in the event your “traditional” 510(k) application is rejected, as disclosed on page 32. In this regard, we note your disclosure on page 31 describing Class III medical devices as “devices for which the FDA has insufficient information to conclude that either general controls or special controls would be sufficient to assure safety and effectiveness....” Additionally:

- tell us why you have not previously submitted a de novo application;
    - tell us why you chose to submit a “traditional” 510(k) application instead of a de novo application; and
    - describe the procedural and substantive differences in the process between “traditional” and “de novo” 510(k) applications.
  - Tell us whether you previously pursued 510(k) clearance, and the results of any such efforts.
4. Substantially revise your response to prior comment 3 to provide us with the location of the specific statements of guidance regarding when you would file your application with the FDA and the reason you were not able to achieve that goal, instead of referring us to a discussion of the regulatory status of your product contained in each of the filings listed in the table. For instance, the table indicates that filings keyed with the letter “H” contained statements disclosing that you were working with a FDA regulatory consultant to determine whether you were eligible to file a 510(k) application instead of a PMA application; however, no such disclosure appears to have been made anywhere in these filings and the disclosures you referenced discuss your intended PMA submission. With respect to the filings keyed with the letter “I” which is specific to a 510(k) application, there does not appear to have been any reference in those filings specifying that the submission “in the process of preparation, documentation and review” would be a 510(k) application instead of a PMA application. Similarly, we note your statement on page 4 of your Form S-1 filed on October 28, 2008 that you anticipated filing your PMA application in December 2008; however, your table only indicates that the disclosure contained references to information in keys “E” and “F” and does not contain any reference to the specific guidance disclosed in this filing about the timing of your submission. Please ensure that your revised table references *what you specifically disclosed regarding when you would file the PMA application* in each of the filings.
5. If the revised table that you provide in response to the comment above indicates that you have revised your disclosed projections regarding the timing of your FDA application, please include in appropriate sections of your prospectus disclosure clearly explaining the nature, frequency, and duration of these revisions. Refer to the guidance in Regulation S-K Item 10(b)(3)(ii). In circumstances where you disclosed that you would have sufficient financing but then determined that you did not have sufficient financing, ensure that your disclosure explains clearly why the financing proved to be inadequate; for example, currently page 9 of your document includes apparently contradictory disclosure that you previously thought you had sufficient financing to complete the FDA approval process but were delayed due to lack of financing.
6. We note your disclosure regarding substantial equivalence. With a view toward clarified disclosure, please tell us where you disclose the scope and duration of the patents that you mention on page 15. Also, also tell us where you disclose the material terms,

including termination provisions, of the patent license agreements; tell us which exhibit represents those agreements. Please tell us the date on which your material patent expires on the technology that you disclose you have been seeking to develop.

United States Government Regulation, page 31

7. With a view toward clarified disclosure, please tell us whether you believe that the 90-day and 180-day periods that you disclose represent the typical amount of time for the review process to be completed.

Development History, page 33

8. Please disclose the reasons for the “new inclusion criteria.”

Global Commercialization Update, page 36

9. We note your disclosure added in response to prior comment 4. For each jurisdiction in which you product is marketed or sold without required regulatory approval, please disclose the penalties to which you could be subject by that jurisdiction.

Legal Proceedings, page 40

10. Please file the consent of counsel whose opinions you disclose.

Exhibit 5.1

11. Refer to the fourth paragraph of this exhibit. The opinion that you file to satisfy your obligation under Regulation S-K Item 601(b)(5) should not assume any of the material facts underlying the opinion or facts that are readily ascertainable, nor may it assume conclusions of law that are a necessary requirement of the ultimate opinion given. Please file a revised opinion accordingly.
12. With respect to the penultimate paragraph of the opinion:
  - Given the date limitation, please provide an opinion that is dated as of the date that your registration statement becomes effective.
  - The opinion that you file to satisfy your obligation under Regulation S-K Item 601(b)(5) may not include a limitation on reliance. Please file a revised opinion accordingly.
13. The caption mentioned in the last paragraph of this exhibit does not exist in your prospectus. Please file a revised exhibit accordingly.

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We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Mary Beth Breslin at (202) 551-3625 or me at (202) 551-3617 with any questions.

Sincerely,

Russell Mancuso  
Branch Chief

cc (via facsimile): Robert B. Macaulay, Esq. – Carlton Fields, P.A.