ImaSight GET CLEAR

AUG 2 5 2009

2. 510K SUBMISSION – ABBREVIATED – SUMMARY

1. Device type and name: ImaSight 4600 Digital Radiographic Sensor

2. Submitter: ImaSight Inc.
   10-925 de la Carrière Blvd.
   Gatineau, Quebec
   Canada J8Y 6W5

   Contact person: Jean Caseault
   President
   Tel: (613) 266-4872
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   Date prepared: August 11, 2009

3. Device name: ImaSight 4600 Digital Radiography Sensor

4. Device classification: Class II, 892.1680 (KPR)

5. Product Code: 90MQB

6. Basis for the submission: New device

7. Predicate device: Xplorer 1800 Digital Radiographic System (K063247)

8. Device description: The ImaSight 4600 is a digital radiographic sensor which automatically collects x-ray images from an x-ray source. The ImaSight 4600 sensor collects x-rays and converts them into a computer images for display on a computer. The sensor does not have an x-ray source, which is provided by independent manufacturers. The sensor comes with an acquisition box and a computer, which holds the display and processing software.

9. Indications for use: The ImaSight 4600 is intended for use by a qualified doctor or technologist on both adult and paediatric patients for taking diagnostic radiographic exposures of all body parts of the patients. The Imasight 4600 provides digital image capture and is intended to replace radiographic film/screen. The x-ray generator, x-ray tube and associated equipment are not provided with the proposed sensor. The ImaSight 4600 is not intended for mammography.

10. Comparison with predicate device: Based on performance tests, the ImaSight 4600 is substantially equivalent to the Xplorer 1800. The ImaSight 4600 produces images of similar quality and performance characteristics that are equivalent to those of the Xplorer 1800. Both systems use the same 16-megapixel CCD imaging sensor technology.
    a. Non-clinical tests: The sensor has been evaluated for performance, biocompatibility, effectiveness, thermal, electrical and mechanical safety and is substantially equivalent to the predicate device. The design, development and production of the sensor conforms to 892.1680, ISO 9001 and ISO 13485 quality systems.
    b. Clinical tests: A set of images have been submitted along with the equivalent images from the predicate device.
    c. Conclusion: the device was evaluated against the predicate device (Xplorer 1800) and was found to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Imasight, Inc.
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

AUG 2 5 2009

Re: K092307
Trade/Device Name: Imasight 4600 Digital Radiography Sensor
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: KPR
Dated: July 29, 2009
Received: July 30, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092307

Device Name: ImaSight 4600

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092307