K051980

AUG 19 2005

510 (k) Summary

Submitters Information

Name:	Imaging Sciences International Inc.
Address:	1910 North Penn Road Hatfield PA, 19440
Phone Number:	215-997-5666
Fax Number:	215-997-5665
Person To Contact:	David W. Cowan Vice President of Engineering, Quality Assurance and Government Compliance
Date Of Summary:	July 20, 2005
Trade Name Of The Device:	DVT Scanner
Common Or Usual Name:	Computed Tomography X-ray System
Classification Name:	Computed Tomography X-ray System

Substantial Equivalence Claim: The Imaging Sciences International Inc. DVT Scanner is substantially equivalent to the devices listed below:

Device:	NewTom QR – DVT 900
Manufacturer:	NIM s.r.1. Via Silverstrini, 20 37135 Verona Italy
510 (k) Number:	K003787

Device:	Advantage 3-D XR
Manufacturer:	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex France
510 (k) Number:	K945375

Device:	3D Accu-I-tomo XYZ Slice View Tomograph
Manufacturer:	J. Morita Manufacturing Corporation 680 Higashihama Minami-cho, Fushimi-ku Japan
510 (k) Number:	K030450

Description Of The Device: The DVT Scanner is a dedicated X-Ray imaging device that acquires a 360 degree rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The DVT Scanner can measure distances and thickness on two dimensional images. Images produced by the DVT Scanner can be printed or exported on magnetic and optical media.

The DVT Scanner gantry is comprised of an X-ray source, image detector, and motorized gantry. The gantry facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector, transforms them into three dimensional images and displays them on the workstation monitor for viewing.

Intended Use Of The Device: The DVT Scanner is an X-ray imaging device that constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Comparison with Predicate Devices: The DVT Scanner reconstructs a three dimensional model from X-ray images similar to the model obtained using the predicate

devices. It displays either two-dimensional cross-sections or three dimensional views and allows the user to take measurements on reconstructed images.

Conclusions: The DVT Scanner Acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (e.g. electrical, mechanical, thermal, radiation, incorrect measurements or misdiagnosis) are controlled by the design development, verification and validation process which includes a risk management system.

The DVT Scanner complies with the requirements of 21 CFR 807.87 and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2005

Mr. Dave Cowan
Vice President of Engineering, Quality
Assurance and Government Compliance
Imaging Sciences International, Inc.
1910 North Penn Road
HATFIELD PA 19440

Re: K051980
Trade/Device Name: DVT Scanner
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 20, 2005
Received: July 27, 2005

Dear Mr. Cowan:

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051980

Indications for Use

510(k) Number (if known): K051980

Device Name: DVT Scanner

Indications For Use: The Imaging Sciences International Inc. DVT Scanner constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051980