K030450

MAY 06 2003

510(k) SUMMARY

J. Morita Manufacturing Corporation
3D Accu-I-tomo XYZ Slice View Tomograph

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	3D Accu-I-tomo XYZ Slice View Tomograph
Common Name:	Cone beam x-ray CT
Classification Name:	computed tomography x-ray system
Product Code:	JAK

J. Morita Manufacturing Corporation
680 Higashihama Minami-cho, Fushimi-ku
Kyoto 612-8533
Japan
Telephone: 011-81-75-605-2305
Facsimile: 011-81-75-605-2350
Date Prepared: January 20, 2003

Intended Use

The 3D Accu-I-tomo is an x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dento-maxillofacial areas, for use in diagnostic support. The device accomplishes this task by reconstructing a three-dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device can also be used for fluoroscopy during surgery, mostly for ENT and TMJ applications and mostly with a contrast medium. The device is operated and used by physicians, dentists, and x-ray technologists.

Technological Characteristics and Substantial Equivalence

The C-arm assembly is mounted to the support column, which has an x-ray control panel for loading factors, an emergency stop switch, and a remote control for patient positioning. The C-arm assembly includes an image intensifier and an x-ray head with a beam-limiting device. The control box, which includes operational lights and an x-ray emission button, is typically placed in a separate room from the rest of the system. The patient chair includes an armrest and a headrest to fix the patient's head during the x-ray emission. An optional headrest for ENT applications is available which can be replaced with the headrest for dental applications.

A Windows-based personal computer is connected to the 3D Accu-I-tomo, on which is installed "3DXD" driver software and "3DX Integrated Information System" application software. For the network environment, "3DXD" driver software and "3DX Integrated Information System" are installed in the server computer and "3DX Integrated Information System" is installed in the client computer. The Windows-based personal computer is not manufactured by J. Morita Manufacturing Corp.

The 3D Accu-I-tomo operates in either CT mode or Fluoroscopic mode. In CT mode, it generates three-dimensional images that make possible precise diagnosis of the head and neck areas. It produces high resolution images and uses less x-radiation in comparison with conventional computed tomography x-ray systems. Fluoroscopy is available using the same x-ray head and image intensifier that are used for the CT mode. Fluoroscopy is mainly used with a contrast medium for ENT applications and surgery of the TM Joint. The same device can provide three-dimensional images and fluoroscopy. Both two- and three-dimensional images are taken for diagnosis before and after surgery. The fluoroscopic setting has three modes: a fluoroscopic moving image mode, a still image mode, and a testing mode. In the testing mode, it can take but not save a moving image.

The 3D Accu-I-tomo is substantially equivalent to the (i) Siemens Medical Systems' Siremobil C02 (K#973598), (ii), Siemens Siremobil Iso-C 3D Imaging Option (K#003266), and (iii) NIM s.r.l.'s NewTom Model QR-DVT 9000 (K#003787). The 3D Accu-I-tomo has similar general intended uses, principles of operation, and technological characteristics as the previously cleared predicate devices. Although there are minor difference in the characteristics of the 3D Accu-I-tomo and the predicate devices, these differences do not raise new questions of safety or efficacy.

The software used in the 3D Accu-I-tomo has been successfully validated by J. Morita Manufacturing Corp. The software validation report describes: the development process for the device's firmware; and driver software and application software installed in Windows-based personal computer; the software change control and code revision procedures; the system and software requirements; the software handling and storage procedures; a hazard analysis; and a software/firmware certification that the company followed the above-described procedures and policies.

The 3D Accu-I-tomo was tested to ensure compliance with UL2601-1 and IEC 60601-1, and its collateral standards, and it complied with the applicable requirements. The 3D Accu-I-tomo will be tested and will comply with the applicable requirements of 21 CFR Subchapter J prior to marketing. The 3D Accu-I-tomo also passed the image quality testing.

The 3D Accu-I-tomo complies with the applicable thermal, mechanical, and electrical safety requirements of UL2601-1, IEC 60601-1, and its collateral standards and will comply with the applicable requirements of 21 CFR Subchapter J prior to marketing.

The 3D Accu-I-tomo uses biocompatible plastics on all body contacting surfaces, such as the head/chin band, headrest cushion, headrest, headrest support, side head support, subnasal point rest and ear piece, etc. Such plastics have been used in predicate devices or widely used in other medical applications in which the plastic is in contact with the patient's body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

J. Morita Manufacturing Corporation
% Mr. Keith A. Barritt
Fish & Richardson, P.C.
1425 K Street, N. W.
11th Floor
WASHINGTON DC 20005

Re: K030450
Trade/Device Name: 3D Accu-I-tomo XYZ Slice View Tomograph
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: February 10, 2003
Received: February 11, 2003

Dear Mr. Barritt:

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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known):

Device Name: 3D Accu-I-tomo XYZ Slice View Tomograph

Indications For Use: K030450

The 3D Accu-I-tomo is an x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dento-maxillofacial areas, for use in diagnostic support. The device accomplishes this task by reconstructing a three-dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device can also be used for fluoroscopy during surgery, mostly for ENT and TMJ applications and mostly with a contrast medium. The device is operated and used by physicians, dentists, and x-ray technologists.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030450