K103689

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510K) SUMMARY

MAR 17 2011

DATE
December 14, 2010

PRODUCT, CLASSIFICATION NAME
Trade name: Planmeca ProMax 3D Mid
Common name: Tomography x-ray system
Classification: MUH, Class II
Regulation number: 872.1800

MANUFACTURER
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki, Finland
Phone: +358 20 7795 500
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Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person : Bob Pienkowski

INTENDED USE
Planmeca ProMax 3D Mid, is a panoramic and cephalometric x-ray unit, which uses Cone Beam Volumetric Tomography (CBVT) to produce three-dimensional images of the human teeth, jaws and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified health care professionals.

PRODUCT DESCRIPTION
The Planmeca ProMax 3D Max is in principle a conventional digital panoramic/tomography x-ray system with three-dimensional Cone Beam Volumetric Tomography (CBVT) system add on. The product rotates around the patient and takes still images with a flat panel sensor synchronized to x-ray generator pulsing. A 3D reconstruction engine calculates the cylindrical 3-dimensional volume image, which then is viewed in 3D viewing stations.

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SUBSTANTIAL EQUIVALENCE

We consider this product modification to be similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

# K060328	Planmeca ProMax 3D
# K093590	Planmeca ProMax 3D Max

The comparison of characteristics supports substantial equivalence. Planmeca ProMax 3D Mid is as safe and effective as the predicate devices.

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

Mr. Lars Moring
Regulatory Affairs Manager
Planmeca Oy
Asentajankatu 6
Helsinki, Finland FI-00880

MAR 17 2011

Re: K103689
Trade/Device Name: Planmeca Promax 3D MID
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: MUH
Dated: December 14, 2010
Received: December 17, 2010

Dear Mr. Moring:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely ~~yours~~,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Planmeca Promax 3D Mid

Indications For Use:

Planmeca Promax 3D Mid, is a panoramic and cephalometric x-ray unit, which uses Cone Beam Volumetric Tomography (CBVT) to produce three-dimensional images of the human teeth, jaws and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified health care professionals.

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 Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103689