DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 20, 2016

Planmeca Oy
% Lars Moring
Regulatory Affairs Manager
Asentajankatu 6
Helsinki, 00880
FINLAND

Re: K160506
Trade/Device Name: Planmeca ProMax 3D Max, Planmeca Maximity
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 2, 2016
Received: May 5, 2016

Dear Lars 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160506

Device Name
Planmeca ProMax 3D Max
Planmeca Maximity

Indications for Use *(Describe)*

The Planmeca ProMax 3D Max or Maximity is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital X-ray images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K) SUMMARY

DATE
May 2, 2016

PRODUCT, CLASSIFICATION NAME
Trade name: Planmeca ProMax 3D Max or
Planmeca Maximity
Common name: Computed tomography x-ray system
Classification: OAS, Class II
Regulation number: 892.1750

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INTENDED USE
The Planmeca ProMax 3D Max or Maximity is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

PRODUCT DESCRIPTION
The Planmeca ProMax 3D Max or Planmeca Maximity -x-ray unit uses cone beam computed tomography (CBCT) to produce three-dimensional (3D) images of the maxillofacial and ENT anatomies. Two dimensional (2D) images are produced with tomosynthesis method. In CBCT a cylindrical volume of data is captured in one imaging procedure. The data consists of several hundred sample images which are taken from different directions to cover a certain pre-programmed target area. These samples are used for 3D reconstruction (using a separate 3D reconstruction PC) that can be viewed in three dimensions in the Planmeca Romexis program (on a separate PC system). Ethernet computer networking technology is used.

PREDICATE DEVICE
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:

K093590 Planmeca ProMax 3D Max
K103659 Carestream CS 9300

SUBSTANTIAL EQUIVALENCE
The product is principally just the same as in the previous 510(k) #K093590.
The indications for use are expanded to include the ENT area.

The expanded intended use of the Planmeca ProMax 3D Max and the predicate device #K103659 is identical. The compared technical features for imaging technology, FOV, imaging parameters, resolution, and other basic characteristics are matching very closely, and the differences are so small that they do not have any effect on performance in practice. Both devices conform to given international performance standards.

The performance testing for ENT imaging applications was carried out taking clinical images for nose, sinuses, airways, middle ear, temporal bone and vertebrae. The images were reviewed by a specialist and were deemed to be of a clinically usable diagnostic quality.

CONCLUSION
The comparison of characteristics supports substantial equivalence. Planmeca ProMax 3D Max is as safe and effective as the predicate device.