K072574

510(k) Summary
510(k) Number

OCT 18 2007

TAKARA BELMONT CORPORATION
1-1-2 CHOME, HIGASHI-SHINSAIBASHI, CHUO-KU
Osaka 542 Japan
Tel: 81-6-6213-5945
Fax: 81-6-6212-3680
Date Prepared: September 7, 2007
Contact: Tomokuni Hasegawa, Senior VP

1. **Identification of the Device:**
   Proprietary-Trade Name: Alphard Model X178 Dental Cone Beam CT
   Classification Name: Computed Tomography X-Ray System Product Code 90 OAS
   Common/Usual Name: Dental CT

2. **Equivalent legally marketed device:** K052587 3D Accu-I-tomo XYZ Slice View Tomograph, manufactured by MORITA and K063622 Fine Cube, manufactured by YOSHIDA

3. **Indications for Use (intended use)** Alphard is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists..

4. **Description of the Device:** Alphard series 3D X-ray CT realizes wide area imaging by adopting the principle of cone beam CT and using high-resolution wide area flat panel detector (FPD). Alphard series enables dentist to take wide range imaging from small area to wide area with appropriate imaging mode according to various treatment objects. Combination of advanced FPD (dynamic range: 14bit) and micro focus X-ray tube provides high resolution CT image from soft tissue to hard tissue. Our original software AsahiVision freely displays high picture quality 3D image and MPR image.

   Imaging mode and range
   Alphard VEGA in Alphard series (Alphard-3030)
   - D mode (Dental CT mode: imaging area 51 mm in dia. X Height 51 mm)
   - I mode (Implant CT mode: imaging area 102 mm in dia. X Height 102 mm)
   - P mode (Panoramic CT mode: imaging area 154 mm in dia. X Height 154 mm)
   - C mode (Cephalo CT mode: imaging area 200 mm in dia. X Height 179 mm)

   Alphard VEGA in Alphard series (Alphard-2520)
   - D mode (Dental CT mode: imaging area 51 mm in dia. X Height 51 mm)
   - I mode (Implant CT mode: imaging area 102 mm in dia. X Height 102 mm)
   - P mode (Panoramic CT mode: imaging area 169 mm in dia. X Height 119 mm)

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, test laboratory and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Manu-facturer	J. Morita Manufacturing. Corporation. K052587	Yoshida Dental K063622	TAKARA BELMONT
Product Name	3D Accu-I-tomo XYZ Slice View Tomograph	FineCube	Alphard
Indication for use	The 3D Accu-I-tom0 is an x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial 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.	FineCube is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists.	Identical to Yoshida: an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists
Specification comparison	Focal spot: 0.5mm x 0.5mm Tube voltage: 60 ~ 90kV Tube current: 1 ~ 10mA Exposure time: Under 18sec Input: 2.0kVA Power supply: AC100V , 50/60Hz Projection mode: CT, Panoramic Detector dimension: 109mm x 111mm	Focal spot: 0.2mm×0.2mm Tube voltage: 90kV Tube current: 4mA Exposure time: 19-37 sec Input: 1.5kVA Power supply: AC120V , 60Hz Projection mode: CT Detector dimension: 120mm x 120mm Pixel size: 200μm×200μm Image matrix size: 608 × 616 pixels	Focal spot: 0.6mm×0.6mm Tube voltage 60-100 kV Tube current: 2-15 mA Exposure time: 17 sec maximum Input: 3 kVa . Power supply: AC 220 v, 50/60 Hz. Projection mode: CT, Panoramic Detector dimension: Two sizes available: Varian 2520: 250mm x 200mm Pixel size 127μm x 127μm 1536 x 1920 pixels Varian 3030, 300mm x 300mm, Pixel size 194μm x 194μm 1536 x 1536 pixels

7. Conclusion

After analyzing both bench and user testing data as well as external laboratory testing to applicable standards, it is the conclusion of Takara Belmont Corporation that the Alphard Model X178 Dental Cone Beam CT System is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Takara Belmont Corporation
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K072574
Trade/Device Name: Alphard Model X178 Dental Cone Beam CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 12, 2007
Received: September 13, 2007

Dear Mr. Kamm:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Indications for Use

510(k) Number (if known):

Device Name: Alphard Model X178 Dental Cone Beam CT

Indications For Use:
Alphard Model X178 is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists.

Prescription Use _X_ AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K072574