K063622

**510(k) Summary**
**510(k) Number**

**The Yoshida Dental Mfg. Co., Ltd.**
**1-3-6, Kotobashi, Sumida-Ku**
**Tokyo, JAPAN 130 85164**
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FEB 8 2007

Date Prepared: November 30, 2006

**Contact:** R&D Department (テクニカルセンタ)
Hidenori Watanabe(渡辺英憲)

1. **Identification of the Device:**
   **Proprietary-Trade Name:** FineCube
   **Classification Name:** Computed Tomography X-Ray System Product Code 90 JAK
   **Common/Usual Name:** Dental CT

2. **Equivalent legally marketed device:** Imaging Sciences International Inc. DVT SCANNER K051980; J. Morita Manufacturing. Corporation. 3D Accu-I-tomo XYZ Slice View Tomograph K030450

3. **Indications for Use (intended use)** 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..

4. **Description of the Device:** The FineCube consists of two main elements: (1) The X-Ray generation and acquisition system and (2) the image analysis software. The X-Ray generation/acquisition system creates a cone-shaped x-ray field which is acquired on a flat panel sensor with a resolution of 608 x 616 x 200 µm. FineCube is an X-ray imaging device that constructs a three dimensional model from images taken during a rotational X-ray sequence. FineCube is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects

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**

| **Manufacturer** | **Imaging Sciences International Inc. K051980** | **J. Morita Manufacturing. Corporation. K030450** | **Yoshida Dental** |
|---|---|---|---|
| Product Name | DVT SCANNER | 3D Accu-I-tomo XYZ Slice View Tomograph | FineCube |

| Manufacturer | Imaging Sciences International Inc. K051980 | J. Morita Manufacturing. Corporation. K030450 | Yoshida Dental |
|---|---|---|---|
| Indication for use | The 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. | 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. |
| Specification comparison | Focal spot: 0.6mm<br><br>Tube voltage: 60,80,100,120kV<br>Tube current: 10,15mA<br>Exposure time: 9.6sec<br>Emergency stop method: Emergency stop switch<br>Input: 10kVA<br>Power supply: AC200V<br>Projection mode: CT<br>Detector dimension: 9.7 / 4.5 inch | Focal spot: 0.5mm x 0.5mm<br>Tube voltage: 60 ~ 90kV<br>Tube current: 1 ~ 10mA<br>Exposure time: Under 18sec<br>Emergency stop method: Emergency stop switch<br>Input: 2.0kVA<br>Power supply: AC100V , 50/60Hz<br>Projection mode: CT, Panoramic<br>Detector dimension: 109mm x 111mm | Focal spot: 0.2mm×0.2mm<br>Tube voltage: 90kV<br>Tube current: 4mA<br>Exposure time: 19 / 37sec<br>Emergency stop method: Emergency stop switch<br>Input: 1.5kVA<br>Power supply: AC120V , 60Hz<br>Projection mode: CT<br>Detector dimension: 120mm x 120mm<br>Pixel size: 200μm×200μm<br>Image matrix size: 608 × 616 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 Yoshida Dental that the FineCube Dental 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

The Yoshida Dental Mfg., Co., Ltd.
% Daniel Kamm, P.E.
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PO Box 7007
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FEB 8 2007

Re: K063622
Trade/Device Name: FineCube Dental CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: December 1, 2006
Received: December 20, 2006

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 (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.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

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 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~~): K063622

Device Name: FineCube Dental CT System

Indications For Use:
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.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063422