April 25th, 2022

Dentimax
% Korina Akhondzadeh
Consultant
KARA & Associates, Inc.
6965 El Camino Real, Suite 105-482
CARLSBAD California 92009

Re: K092547
Trade/Device Name: Dentimax Digital X-Ray Imaging System Sensor Size 1, 2, Dentimax USB Control Box
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source X-ray system
Regulatory Class: Class II
Product Code: MUH

Dear Korina Akhondzadeh:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated **October 30th, 2009**. Specifically, FDA is updating this SE Letter because the Product code was incorrectly identified as MUJ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Laurel Burk, OHT7: Assistant Director, Office of In Vitro Diagnostics and Radiological Health, +1 (301 796-5933, Laurel.Burk@fda.hhs.gov.

Sincerely,

Digitally signed by
Laurel M. Burk -S
Date: 2022.04.25
09:53:21 -04'00'

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

DentiMax
% Mr. Korina Akhondzadeh
Sr. Regulatory Consultant
KARA & Associates, Inc.
6965 El Camino Real, Suite 105-428
CARLSBAD CA 92009

OCT 30 2009

Re: K092547
Trade/Device Name: DentiMax Digital X-Ray Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUJ
Dated: August 13, 2009
Received: August 19, 2009

Dear Mr. Akhondzadeh:

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); 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092547

Device Name:

Indications For Use:

DentiMax Digital X-ray Imaging System is intended to be used with standard digital X-ray systems to collect dental x-rays photos and convert them into electronic impulses that may be stored, viewed, and manipulated by dentists for the diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(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 K092547

K092547

510(K) SUMMARY

OCT 30 2009

Submitter's Information:

DentiMax
4115 E. Valley Auto Drive, Suite 101
Mesa, AZ 85206
(480) 396-1798 x 201

Name of contact person:

DentiMax
David J. Arnett
4115 E. Valley Auto Drive, Suite 101
Mesa, AZ 85206
(480) 396-1798 x 201

Date the summary was prepared: **August 4, 2009**

Name of Device:

Trade/Proprietary Name:	DentiMax Digital X-ray Imaging System
Common/Usual Name:	Intraoral Digital X-ray sensor
Classification Name:	Extraoral Source Dental X-ray, Digital System

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Description of the device:

Catalog #: SENSORH1
SENSORH2
USB Control Boxes: SENSORBOXHI and SENSORBOXH2

Digital Dental intraoral Xray Sensor

This device is intended to be used for dental radiographic examination for the diagnosis of diseases of the teeth, jaw, and oral structures.

510(K) SUMMARY (continued)

Indications:

Indications for Use (from labeling): DentiMax Digital X-ray Imaging System is intended to be used with standard X-ray systems to collect dental x-rays photos and convert them into electronic data that may be stored, viewed, and manipulated by dentists for the diagnosis of diseases of the teeth, jaw, and oral structures

Summary of the technological characteristics of our device compared to the predicate device:

The predicate Accent™ Sensor Digital X-ray System, manufactured by Air Technique reference number is K050693 and DentiMax Digital X-ray Imaging System were compared and found to have similar technological characteristics and to be equivalent.