Krugman Technologies, Inc.

September 24, 2002

DEC 13 2002

K023292

510 (k) Summary

Submitter Information:
Krugman Technologies, Inc.
1000 Hart Road Suite 180
Barrington, IL 60010
Phone: (800) 506-9736
Fax: (847) 381-9940
Email: admin@ktinet.net

Name of Device:
Trade Name: Apex HRI Digital Radiography System
Common Name: Intraoral Digital Xray sensor
Classification Name: Unit, Xray, Intraoral (per 21 CFR Section 892.1800)
This is a Class II device
Product Code: MUH

Substantially Equivalent Devices:
Trophy Radiologie RVG Portable Radiovisiography K950532
Mediadent HDXMMD HDX SP xray sensor K002425
Computed Oral Radiology System K933455

Device Description:
Digital dental Intraoral Xray sensor

Intended Use:
This device is used to take dental intraoral diagnostic xrays

Technological Characteristics compared to predicate devices:
The Apex HRI Digital Radiography sensor is identical to the Mediadent HDXMMD HDX SP xray sensor in size, type, and materials used to manufacture the product. The product manufacturer for the Apex and Mediadent devices is Fimet Oy. The Apex HRI Digital Radiography sensor is virtually identical to the Trophy Radiologie RVG Portable Radiovisiography sensor in size, manufacture and materials. The only difference between these and the Computed Oral Radiology System is the type of sensor employed. The Computed Oral Radiolology System uses a CMOS sensor while Apex, Mediadent and Trophy use a CCD sensor. This is a minor difference in design. All four products are used in exactly the same manner and circumstances. All four use the same barrier protection for infection control as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Mr. Michael A. Krugman
President
Krugman Technologies, Inc.
1000 Hart Road, Suite 180
BARRINGTON IL 60010

Re: K023292
Trade/Device Name: Apex HRI Digital Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: September 24, 2002
Received: October 2, 2002

Dear Mr. Krugman:

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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Krugman Technologies, Inc.

September 24, 2002

Indication for Use

510 (k) Number: K023292
Device Name: Apex HRI Digital Radiography System

The Apex HRI Digital Radiography System is designed to replace standard intraoral xray film and film development chemicals used for patient diagnostics in dental practices.

The Apex HRI Digital Xray Sensor is covered with a sterile disposable sheath and positioned in the oral cavity opposite the tooth the dentist wishes to xray. The dental xray tube (which is NOT part of this product) is pointed at the sensor and activated.

The emitted radiation from the xray tube is detected by the sensor and transmitted as a data stream to the computer system that the device is connected to. The imaging software interprets the data stream and displays it as a grey scale image on the monitor of the connected computer system. The grey scale image is the digitally formed xray the dentist will then use for diagnostics.

Prescription Use _____

Sign-Off)
of Reproductive, Abdominal,
diological Devices
Number K023292