APR 2 8 2010

Therametric Technologies, Inc.
351 West Tenth Street • Suite 222 • Indianapolis, Indiana 46202

K093705

510(K) SUMMARY

Applicant

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Contact

Bart D. Collins
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Therametric Technologies, Inc.
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Date of Application

November 27, 2009

Applicant Device

Trade Name:	FluoreCam™
Common Name:	Fluorescence caries detection device
Classification:	Class II
Classification Name:	Fluorescence caries detection laser (21 CFR 872.1745, Product Code NBL)

Predicate Device

Name:	Inspektor™ Pro
510(k) Number:	K040063

Device Description

The FluoreCam™ consists of a handheld instrument that interfaces with custom computer software via a USB connection. The instrument excites the surface of a tooth with light and transmits images of the surface to the software. The software quantifies carious activity using the auto fluorescent property of tooth enamel.

Intended Use

The FluoreCam™ is intended to be used as an aid in the diagnosis of dental caries.

Substantial Equivalence

The FluoreCam™ is substantially equivalent to other legally marketed devices in the United States. The FluoreCam™ functions in a manner similar to and is intended for the same use as the Inspektor™ Pro designed by Inspektor Dental Care.

	FluoreCam™	Inspektor™ Pro
Intended Use	As an aid in the detection of dental caries	As an aid in the detection of dental caries
Device Type	Fluorescence caries detection device	Fluorescence caries detection device
Packaging	Single Use Disposable	Single Use Disposable
Patient-contacting Material	Polypropylene	Polypropylene
Light Source	Light-emitting Diode	Xenon Lamp
Light Wavelength	Peak 405nm	Peak 405nm
Image Sensor	1/4-inch CCD	1/4-inch CCD

Performance and Safety

Safety and performance testing included comparison testing using polarized light microscopy as a gold standard, software/hardware hazard analysis, software verification and validation, and electromagnetic compatibility testing.

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

APR 2 8 2010

Mr. Bart Collins
Director of Dental Instruments
Therametric Technologies, Incorporated
351 West 10th Street, Suite 222
Indianapolis, Indiana 46202-4119

Re: K093705
Trade/Device Name: FluoreCam™
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: April 13, 2010
Received: April 20, 2010

Dear Mr. Collins:

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 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,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093705

Indications for Use

510(k) Number (if known): _____

Device Name: **FluoreCam™**

Indications for Use:

The FluoreCam™ is indicated as an aid in the diagnosis of dental caries.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093705