K090598

5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

5.1 Submitter Details

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DEC 15 2009

5.2 Official Contact

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Submission date: February 25th 2009

5.3 Device Details

Proprietary / Trade Name:	CarieScan PRO
Classification Name:	Laser Fluorescence Caries Detection Device
Product Codes:	NBL
Common / Usual Name:	Dental Caries Detection Device.

5.4 Equivalent legally marketed devices

Performance	-	DIAGNOdent® 2095	K983658.
Safety	-	Apex NRG XFR, Electronic Apex Locator	K071133.

5.5 Indications for Use (Intended Use)

For use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

5.6 Device Description

This submission is for a handheld dental caries detection device which uses the AC impedance spectroscopy technique (ACIST). Single use disposal sensors are connected to the handheld device. The sensor is placed on the tooth site to be measured and a metal lip hook is placed on the patients lip, a small electrical current is passed between the sensor and the lip hook, the signals returned indicate any mineral changes in the tooth structure.

5.7 Comparison of Technological Characteristics

5.7.1 Performance

With respect to performance, the CarieScan PRO is substantially equivalent to the predicate device, DIAGNOdent 2095. The devices are used in the same way for the same purpose, however the technology used is different. The DIAGNOdent uses laser fluorescence, while the CarieScan PRO uses AC impedance spectroscopy.

5.7.2 Safety

A second predicate device has been selected for safety comparison, this is the Apex NRG – Electronic Apex Locator which also uses an impedance technique.

Predicate Comparison Table

Device Characteristics	Candidate Device	Predicate Devices	
	CarieScan PRO	Performance	Safety
		DIAGNOdent	Apex NRG
Intended Use / Indications for Use	For use by dental professionals as an aid in the diagnosis and monitoring of dental caries.	For use as an aid in the diagnosis of dental caries.	To measure the length of the root canal for the purpose of performing root canals and related dental procedures for use by a trained professional in general dentistry.
Target population	Dental Professionals	SAME	SAME
Anatomical Sites	Teeth	SAME	SAME
Where Used	Dental Surgery	SAME	SAME
Energy used and/or delivered	Electrical Impedance	Laser Fluorescence	Electrical Impedance
Power Source	Lithium Polymer Rechargeable Battery	5- AA Alkaline Battery	1- AA Battery
Measurement Method	Comparison of impedance at multi frequencies	Light fluorescence	Comparison of impedance at multi frequencies
Frequencies used for comparison	3kHz – 20kHz	N/A	6.5kHz – 1.3 kHz
Performance*	92.5 % sensitivity 92.5% specificity	80% sensitivity 52% specificity	N/A
Max Applied Current	< 10 µ A	N/A	< 30 µ A

** See Section 12.2, Substantial Equivalence Discussion.*

The CarieScan PRO meets all of the medical safety standards that are applicable, tests have been conducted and certificates have been achieved to demonstrate conformity. This is further detailed in Declarations of Conformity (Section 9) and Electrical Safety (Section 17).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Nikola Skelly
Quality & Regulatory Affairs Manager
CarieScan Limited
Prospect Business Centre, Gemini Crescent
The Technology Park
Dundee
UNITED KINGDOM DD2 1SW

DEC 15 2009

Re: K090598
Trade/Device Name: CarieScan PRO
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: November 6, 2009
Received: November 12, 2009

Dear Ms. Skelly:

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,

for

Anthony D. 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

4 INDICATIONS FOR USE

510(k) Number (if known):

Device Name: CarieScan PRO

Indications For Use: For use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

R.S. Betz DDS for Dr. K.P. Mulroy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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