K102821

PHOENIX DENTAL INC.

"Better Dentistry through Chemistry"

MAKERS OF SUPER SEAL®

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510(k) SUMMARY

MAR 1 1 2011

1. Submitting Applicant Company

1) Name	Phoenix Dental, Inc.
2) Address	3452 West Thompson Road Fenton, Michigan, 48430
3) Contact Person	Jeffrey S. Cox, President/CEO Telephone: 877-463-9905 Facsimile: 810-750-7495
4) Establishment Registration Number	1836322
5) Date	September 22, 2010

2. Name of Device

1) Proprietary Name	**DiscovRED™**
2) Common / Usual Name	Caries Detector
3) Classification Name	Caries Detection Device

3. Legally marketed device to which the submitter claims equivalence - Predicate Device

Caries Detector by Kuraray Medical Inc.	(K012733)
1) Class	II
2) Regulation Number	872.1740
3) Panel	Dental
4) Classification Product Number	LFC
5) Prescription Use Only	Yes

4. Description of device subject to this premarket notification submission

The product, **DiscovRED™**, is classified into the Caries Detection Device category of CFR 21, Section 872.1740.

DiscovRED™, as well as the Predicate Device, Caries Detector, is a red dye agent that when applied to the suspected carious areas of the tooth stains the carious dentine.

DiscovRED™ is a caries detector. Both devices have a two year shelf-life.

DiscovRED™ is for Prescription Use only and not over-the-counter use.

The method of operation and placement of **DiscovRED™** is similar to that of the Predicate Device, Caries Detector. A drop of the detector is applied to the carious dentine, rinsed with water and air dispersed. The stained carious tissue is then removed with a low speed rotary bur. The process may be repeated until there are no more stainable tissues in the cavity.

DiscovRED™ and the Predicate Device do not involve chemical reactions.

DiscovRED™ and the Predicate Device do not use any power-assisted devices such as optical light emitting or electrical energy forms.

5. Statement of the intended use
   The intended use of the device, **DiscovRED™**, is as follows:

   "DiscovRED™ is indicated for use to detect carious dentine."

   DiscovRED™ has the same intended clinical use as the Predicate Device, Caries Detector, of detecting carious dentine when a dental patient presents with an area of suspected tooth decay.

6. Statement of technological characteristics and safety
   DiscovRED™ has similar technological characteristics as the Predicate Device, Caries Detector.

   Both devices are composed of glycol based chemistries in combination with a red dye colorant that is used to stain/detect carious dentine of the tooth.

   The safety of **DiscovRED™** is very similar to the commercially available Predicate Device, Caries Detector. Both devices must be handled by a dental professional, i.e. dentist, according to their Instructions for Use and Material Safety Data Sheets.

   The two devices' main ingredients, polyethylene glycol for **DiscovRED™** and propylene glycol for Caries Detector, have similar potential health effects. Repeated or prolonged exposure of either product is not known to aggravate any medical condition.

   The first aid measures of both devices are similar in that for any skin contact, wash the area with soap and water, and for eye contact, flush with water and seek medical attention. For inhalation, remove to fresh air, and for ingestion, rinse the mouth with water and spit into sink.

   Toxicological data on the primary ingredients of both **DiscovRED™** and Caries Detector are also similar; however, LD_{50} values for oral toxicity indicate that the primary ingredient in Caries Detector, propylene glycol, is more toxic (lower values) than the primary ingredient, polyethylene glycol, in **DiscovRED™**. Therefore, one may summize that **DiscovRED™** is less toxic than the commercially available Predicate Device, Caries Detector. The small amount, less than one drop, used on a micro sponge in a single application of the device is unlikely a sufficient amount to cause harmful affects to a human. The Instructions for Use and MSDS information should be followed.

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

Mr. Jeffrey S. Cox
President/ Chief Executive Officer
Phoenix Dental, Incorporated
3452 West Thompson Road
Fenton, Michigan 48430

MAR 1 1 2011

Re: K102821
Trade/Device Name: DiscovRED™
Regulation Number: 21 CFR 872.1740
Regulation Name: Caries Detection Device
Regulatory Class: II
Product Code: LFC
Dated: March 4, 2011
Received: March 7, 2011

Dear Mr. Cox:

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,

Anthony D. Watson

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

Enclosure

Indications for Use

510(k) Number: K102821

Device Name: **DiscovRED™**

Indications for Use:

DiscovRED™ is indicated for use to detect carious dentin.

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

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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