K043156

510(k) Summary

APR 2 8 2005

1. Name/Address of Submitter : NEKS Technologies
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Laval, Quebec H7V 4A9
Canada

2. Contact Person : Nathalie H. Tremblay
President and CEO
Phone : (450) 973-3598
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3. Date Summary Prepared : April 19, 2005

4. Device Name : D-CARIE

5. Predicate Devices : Detectar System (K023367)
DIAGNOdent Laser Fluorescence Caries Detection Device (K983658)
Alpha 4 LS Automated Microtiterplate Processor (K973638)
Dental explorers [510(k) exempt]

6. Device Description and Intended Use :

Similar to the Diagnodent the D-CARIE is indicated for use in aiding in the diagnosis of dental caries. The D-CARIE probe is similar in intended use, size, and shape to a Diagnodent probe tip. Identical to the technology in the Detectar the D-CARIE probe contains an optical fiber that reads the optical signature of suspicious areas and converts it into an electrical signal. From that electrical signal a computer analysis identifies areas that need further examination.

7. Brief Description of Clinical and Non-clinical Testings :

Two *in vitro* and one *in vivo* evaluations comparing the D-CARIE with a Diagnodent were conducted by experienced clinicians. Moreover a third *in vitro* evaluation was conducted to examine the quality of detection on "special situations". In these tests, the D-CARIE was found equivalent to Diagnodent.

8. Conclusion Drawn : Substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2005

NEKS Technologies, Incorporated
C/O Mr. Charles H. Kyper
Regulatory Affairs Consultant
Kyper & Associates
208 Barrington Overlook Drive
Durham, North Carolina 27703

Re: K043156
Trade/Device Name: D-Carie
Regulation Number: 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: March 29, 2005
Received: April 1, 2005

Dear Mr. Kyper:

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.

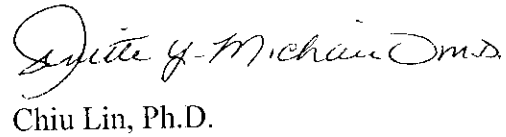
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Section 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K043156

Device Name: D-Carie

Indication for Use: D-Carie is indicated for aiding in the diagnosis of dental carries

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Concurrence of CDRH Office of Device Evaluation

Prescription Use X OR Over-the-counter Use ____
(per 21CFR 801.109)

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

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