K063321

# 510(k) Summary

**Neks Technologies, Inc.**
**2816, Joseph Armand Bombardier**
**Laval, Quebec, Canada,H7P 6E2**
**Contact Person :**
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**October 31, 2006**

MAR 3 0 2007

1. Identificatioin of the device :

   D-Carie/Detectar Models : N121, N123, N133, N134, N135 & N138

2. Predicate Devices:

   DIFOTI System for Dental Examinations, Electro-Optical Sciences, Inc.(K991098)

   Fiberoptic transillumination (FOTI) fiberoptic dental imaging systems-preamendment, various manufacturers (510(k) exempt)

   IN EXAM INTRAORAL DENTAL X-RAY SYSTEM, Kavo America (KO50019) and other dental X-Rays System from various manufacturers.

   Dental explorer for clinical examination, various manufacturer (510(k) exempt)

   D-CARIE, MODEL N121-M1, Neks Technologies (K043156)

   DETECTAR, MODEL N123-MI, Neks Technologies (K023367)

3. Device Description and Intended Use:

   The indication of use of the D-Carie is extended to include aid for diagnosis of inteproximal dental caries. This feature, an object of current submission, is similar in intended use to bitewings x-rays clichés, FOTI/DIFOTI, or visual exam with a manual dental explorer for interproximal caries detection. The D-Carie probe contains optical fibers that read the optical scattering characteristic of dental carie thru healthy enamel structure above (the marginal ridge over the vulnerable inteproximal area) and convert it into an electrical signal. From that signal a computer analysis identifies the dental caries.

   The device can be in either in a new handheld or a tabletop (original) format with the addition or not of the calculus detection feature of the

Detectar. Combining features or changing to miniaturized battery powered format does not change the intended use of each functions.

4. Brief Description of Clinical and Non-clinical Testing:

In vitro and in vivo studies were conducted to assess both sensitivity and specificity for the D-Carie inteproximal detection. Using bitewings clichés or histological observation as a gold standard, studies have shown that this function is at least equivalent in efficiency to the FOTI/DIFOTI devices or visual examination.

Also bench tests (measuring optical electromagnetic power output and its spectral distribution), in vitro and in vivo trials have shown that : 1) D-Carie and Detectar performance are equivalent to when they these functions are combined in a single unit and 2) that the handheld format (Mini) is at least equivalent to the tabletop version originally presented in all important aspects.

5. Conclusions Drawn :

D-Carie inteproximal caries detection is substantially equivalent to the cited predicated devices.

Combining D-Carie and Detectar in the same device (Tabletop Duo Model N133) is substantially equivalent to D-Carie and Detectar in individual units.

The handheld format (Mini Detectar Model N134, Mini D-Carie Model N135 and MiniDuo Model N138) is substantially equivalent to the tabletop format.

These conclusions are based on indications for use, bench, in vitro and in vivo clinical trials, as well as EMC and electrical safety testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Naim Karazivan, D.M.D
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MAR 3 0 2007

Re: K063321
Trade/Device Name: D-Carie/Detectar
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: March 8, 2007
Received: March 12, 2007

Dear Dr. Karazivan:

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.

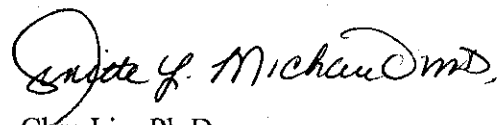
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Enclosure

K063321

# Indication for Use

**510(k) Number (if known):**_____

**Device Name: D-Carie/Detectar**

**Indication for Use: Aid in diagnosis of dental pits and fissures and interproximal caries and aid in the detection of dental calculus.**

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**Concurrence of CDRH Office of Device Evaluation**

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

Susan Runner

(Sign-Off)
sion of Anesthesiology, General Hospital,
ection Control, Dental Devices
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