JUN 2 4 2004

INSPEKTOR
DENTAL CARE

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Development & production
Quellijnstraat 92
1072 XX Amsterdam
T. +31 20 676 4988
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K040063

510(k) Summary

4.1. Applicant

Name	Inspektor Dental Care bv
Address	(Head office) Pieter Baststraat 21-27 1071 TV Amsterdam
Telephone	+31 20 470 1512
Fax	+31 20 679 3183
e-mail	idc@inspektordentalcare.com
Establishment Registration number	not available

Contact Person	Elbert Waller
Address	Inspektor Dental Care bv (Development & Production) Quellijnstraat 92 1072 XX Amsterdam Netherlands
Telephone	+31 20 676 4988
Fax	+31 20 679 3183
e-mail	e.waller@inspektor.nl

4.2. Date summary prepared
June 17, 2004

4.3. Name of the Device

Proprietary/trade name	: Inspektor™ Pro
Common name	: Dental Fluorescence Examination Device
510(k) Number	: K040064

4.4. Predicate Devices:
KaVo DIAGNOdent, K983658

4.5. Device description
The Inspektor™ Pro consists of a systembox equipped with a handpiece, mounted in a trolley together with a computer, a monitor, mouse, keyboard and footswitch.

4.6. Intended Use
The Inspektor™ Pro is intended to be used as an aid in the diagnosis of dental caries.

4.7. Indications for use
The Inspektor™ Pro is indicated as an aid in the diagnosis of dental caries.

4.8. Substantial Equivalence
Inspektor™ Pro resembles the predicate device DIAGNOdent as an aid in the diagnosis of dental caries.

I hereby declare that the information stated in this 510(k) summary is truthful and accurate.
Date June 17, 2004
Place Amsterdam
Signature:

Elbert Waller
(CDO Inspektor Dental Care BV)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Inspektor Dental Care BV
Mr. Elbert Waller
(Development & Production)
Quellijnstraat 92
1072 XX Amsterdam
NETHERLANDS

Re: K040063
Trade/Device Name: Inspektor™ Pro
Regulation Number: 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: April 8, 2004
Received: April 13, 2004

Dear Mr. Waller:

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.

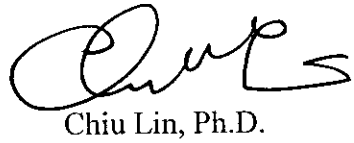
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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 STATEMENT

510(k) Number: **K040063**

Device Name: **Inspektor™ Pro**

Indications for use:
The Inspektor™ Pro is indicated as an aid in the diagnosis of dental caries.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional format 1-2-9)

Susan Runner

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

510(k) Number: K040063