JUN 30 1999

510(k) Summary

K991098

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Electro-Optical Sciences, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Electro-Optical Sciences chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: **DIFOTI Dental Examination System**

Owner/Operator: Electro-optical Sciences, Inc.
1 Bridge Street, Suite 15
Irvington-on-Hudson, NY 10533

Manufacturing Site: Electro-optical Sciences, Inc.
1 Bridge Street, Suite 15
Irvington-on-Hudson, NY 10533
Registration # Not yet assigned

Device Generic Name: Dental examination system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class I, General Controls (21 CFR 872.4620, and 872.6640).

Predicate Devices: Fiberoptic transillumination (FOTI) fiberoptic dental imaging systems – preamendment, various manufacturers

Computer Oral Radiography System (K933455) and CDR-CAM (K963778) Schick Technologies, Inc.

Product Description:
The DIFOTI device is a dental examination system that utilizes visible light delivered with fiberoptic technology for transillumination imaging of teeth as a technique for visualizing dental caries. An electronic charge-coupled device (CCD) camera is used to capture the image(s), a small PC serves for for data acquisition and storage, and a computer monitor is used for image visualization.

Indications for Use:
The DIFOTI System for Dental Examinations is indicated for detection of frank or incipient caries lesions above the gum line, and for monitoring the progression of such lesions.

Safety and Performance:
Safety and performance testing included image quality evaluation, software/hardware hazard analysis, *in-vitro* vs. *in-vivo* performance evaluation, and software verification and validation.

Conclusion:
Based on the indications for use, technological characteristics, comparison to predicate devices and performance testing, the DIFOTI Dental Examination System has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1999

Electro-Optical Sciences, Incorporated
c/o Ms. Pamela Papineau
Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K991098
Trade Name: DIFOTI™ System
Regulatory Class: I
Product Code: EIA
Dated: March 29, 1999
Received: April 1, 1999

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Rebecca Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): _____

Device Name: DIFOTI System for Dental Examinations

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991693