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K993300

Appendix D
510(k) Summary

September 23, 1999

1. Submitted for Photonics Optics GESMBH by the initial importer and distributor, Fiber Imaging Technologies, Inc., 326 Clark Street, Worcester, Massachusetts, 01606. Submission correspondent and contact: Mr. Joseph Ress, Medical Device Regulatory Consultants, 45 Pontiac Road, Newton, MA 02168, whose telephone and FAX number is (617) 965-7714.

2. Trade Name of the Device: Coldsource PL3000

Common Name: Light source

Classification Name: Endoscope and Accessories, Product code: KOG (per 876.1500)

3. Predicate Device: K890716, Luxtec Model 3150 Light Source

4. Description of the Device: The Photonics Coldlightsource PL3000 is a lightsource for fiberoptic cables, with a 230/240 volt version which conforms to ENEC 11, EN60601, EN55011, and UL 2601. The 120 volt version is manufactured to the same requirements of these standards, and has been submitted for approval. Approval is anticipated in the immediate future.

5. Intended Use: To provide illumination through light-conducting devices such as fiberoptic cables.

6. Comparison to Predicate Device:

Feature	Photonics Model PL3000	Luxtec Model 3150S
Power requirements	115/230VAC 60 Hz	115VAC 60 Hz
Power consumption	approx 200 W	approx 200W
Lamp type	Halogen	Halogen
Lamp Wattage	150 Watts	150 Watts
Color Temperature	3400° Kelvin	3250° Kelvin
Light Intensity Control	Yes	Yes
Fiberoptic cable connection	yes	yes

7. Conclusions: Photonics Optics GMBH believes that based upon the foregoing, the Model PL3000 is substantially equivalent to the predicate device (K890716) marketed by Luxtec Model 3150S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Fiber Imaging Technologies, Inc.
c/o Mr. Joseph Ress
Medical Device Regulatory Consultants
45 Pontiac Road
Newton, MA 02168

Re: K993300
Photonics Coldlightsource PL3000
Dated: September 24, 1999
Received: October 1, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FCW

Dear Mr. Ress:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number: K993300

Device Name: Photonics Coldlightsource PL3000

Indications for Use:

The Photonics Coldlightsource PL3000 is indicated for use to provide illumination through light-conducting devices such as fiberoptic cables.

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

Concurrance of CDRH, Office of Device Evaluation (ODE)

Perscription Use YES OR Over-The-Counter Use NO

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993300