K062259

510(k) Summary

Submitter's Name:	iScience Surgical Corporation
Submitter's Address:	4055 Campbell Avenue, Menlo Park, CA 94025
Submitter's Telephone:	Phone (650) 421-2700
Contact Name:	Grace Bartoo
Date Summary was Prepared:	May 3, 2006
Trade or Proprietary Name:	iScience Surgical Fiberoptic Illuminator
Common or Usual Name:	Fiberoptic Illuminator (FI)
Classification Name:	Endoilluminator

AUG 15 2006

Predicate Devices:

Device Name	510(k) Number
Synergetics Synerlight Fiberoptic Illuminator	K964005
HEXON Illumination System	K973229

Description of the Device and Summary of the Technological Characteristics:

The iScience Surgical Fiberoptic Illuminator (FI) is a portable light source intended to provide illumination during anterior and posterior segment ophthalmic surgery. It is designed to be used only with the iScience Surgical iTrack Ophthalmic Microcannula to illuminate tissues during advancement into intraocular structures of the anterior and posterior segment.

The FI consists of a splash proof sheet metal enclosure with panel mounted rocker switches for operational control, and a custom light output connector. The FI houses a laser diode illumination source, and is specific for the iScience Surgical iTrack Ophthalmic Microcannula. The FI is not intended to be sterilized or placed in a sterile enclosure.

The FI has a custom designed light output connector that contains two redundant safety interlock switches. These switches, in conjunction with electronic circuitry in the FI, ensure that laser light can only emanate from the laser aperture when an iScience Surgical iTrack Ophthalmic Microcannula is installed in the connector. The interlock switches independently detect the proper insertion of the iScience Surgical iTrack Ophthalmic Microcannula into the connector, ensuring that the microcannula is fully engaged and retained in the connector before laser output is enabled.

Substantial Equivalence:

The product's technical features are substantially equivalent to the Synergetics Synerlight Fiberoptic Lightsource (K964005) marketed by Synergetics, Inc., and the HEXON Illumination System (K973229) marketed by Dutch Ophthalmic Research Center. Like the iScience Surgical Fiberoptic Illuminator, these predicate devices also are indicated for illumination during anterior and posterior segment ophthalmic surgery.

The iScience Surgical Fiberoptic Illuminator is designed to be used exclusively with the iScience Surgical iTrack Ophthalmic Microcannula. The iScience Surgical FI differs from the predicate devices by utilizing a laser diode as the light source as compared to a metal halide light source. The use of a laser diode illumination source eliminates the need for filtering out potentially harmful wavelengths and lowers the power requirements of the device. The maximum output power of the device is 200 μW, significantly less than either the Synerlight or HEXON Illumination Systems. Additionally the iScience Surgical FI is battery powered compared to AC powered.

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In-vitro testing of the iScience Surgical FI and the HEXON Illuminator, both used with the iScience Surgical iTrack Ophthalmic Microcannula in enucleated cadaver eyes, demonstrated equivalent results. Both illumination sources provided sufficient illumination at the tip of the iScience Surgical iTrack Ophthalmic Microcannula to advance it into intraocular structures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2006

iScience Surgical
c/o Neil E. Devine Jr.
Intertek Testing Services
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K062259
Trade/Device Name: iScience Surgical Fiberoptic Illuminator
Regulation Number: 21 CFR 876.1500
Regulation Name: Fiberoptic Illuminator
Regulatory Class: II
Product Code: MPA
Dated: August 3, 2006
Received: August 4, 2006

Dear Mr. Devine:

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,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):
Device Name: iScience Surgical Fiberoptic Illuminator

Indications for Use:

The iScience Surgical Fiberoptic Illuminator is indicated for illumination during anterior and posterior segment ophthalmic surgery.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

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