

5.0 510(k) Summary

JUL 18 2008

Submitter's Name: iScience Interventional Corporation
 Submitter's Address: 4055 Campbell Avenue
 Submitter's Telephone: Phone (650) 421-2700
 Fax (650) 239-3697
 Contact Name: Grace Bartoo
 Date Summary was Prepared: June 11, 2008
 Trade or Proprietary Name: iScience Interventional Canaloplasty Microcatheter
 Common or Usual Name: Ophthalmic Microcatheter
 Classification Name: MPA, 21 CFR 876.1500 Endoscope and accessories
 HMX, 21 CFR 886.4350 Manual ophthalmic surgical instrument

Predicate Devices:

Device Name	510(k) Number
iScience Surgical Ophthalmic Microcannula	K041108
Endolight End Irrigating Endoilluminator	K970882
True Light End Irrigating Endoilluminator	K973293

Description of the Device Subject to Premarket Notification:

The iScience Interventional Canaloplasty Microcatheter is a flexible microcatheter designed to allow atraumatic catheterization of spaces in the eye for infusion and aspiration of fluids during surgery. The device allows catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma. The microcatheter incorporates an optical fiber to allow transmission of light to the microcatheter tip for surgical illumination and guidance. The device is provided sterile and is intended for single use.

Indications for Use

The iScience Interventional Canaloplasty Microcatheter is indicated for fluid infusion and aspiration during surgery. The iScience Interventional Canaloplasty Microcatheter is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

Technical Characteristics

The intended use and technological features of the iScience Interventional Canaloplasty Microcatheter do not substantially differ from the legally marketed predicate devices. The iScience Interventional Canaloplasty Microcatheter and the predicate device(s) have similar intended uses and methods of operation.

Performance Data

The iScience Interventional Canaloplasty Microcatheter has been shown to conform to the following standards, practices, and guidance:

STERILIZATION

- ANSI/AAMI/ISO 11137-1995, *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization.*

BIOCOMPATIBILITY

- ISO 10993-1, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*
- ISO 10993-5, *Biological Evaluation of Medical Devices - Part 5: Tests for in Vitro Cytotoxicity*
- ISO 10993-10, *Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Delayed-Type Hypersensitivity*
- ISO 10993-12, *Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials*

SHELF-LIFE AND PACKAGING INTEGRITY

- ANSI/AAMI/ISO 11607-2000, *Packaging for Terminally Sterilized Medical Devices.*

RISK MANAGEMENT

- ISO 14971:2000, *Medical Device – Application of Risk Management to Medical Devices.*

The device also underwent testing to ensure that performance requirements were met.

DIMENSIONAL AND MECHANICAL TESTING

- Tensile Strength of Joints
- Static Burst
- Fluid Infusion Line Leakage
- Aspiration
- Light Transmission

PRECLINICAL STUDIES

- Ex-vivo studies of accessing Schlemm's canal using Canaloplasty Microcatheter

CLINICAL STUDIES

- A multi-center prospective study to evaluate the safety and efficacy of circumferential viscodilation and tensioning of the inner wall of Schlemm's canal with the Canaloplasty Microcatheter to reduce intraocular pressure in adult patients with open angle glaucoma.

Basis for Determination of Substantial Equivalence:

The indications for use for the iScience Interventional Canaloplasty Microcatheter are similar to the predicate devices cited in this application. The safety of the materials used for the manufacture of the iScience Interventional Canaloplasty Microcatheter has been demonstrated with biocompatibility testing. Performance testing demonstrates that the iScience Interventional Canaloplasty Microcatheter is functionally equivalent to the predicate devices.



JUL 18 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

iScience Interventional Corporation
% Grace Bartoo, Ph.D., RAC, CBA
Regulatory Consultant
4055 Campbell Avenue
Menlo Park, CA 94025

Re: K080067

Trade/Device Name: iScience Interventional Canaloplasty Microcather
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA, HMX
Dated: June 11, 2008
Received: June 13, 2008

Dear Dr. Bartoo:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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

4.0 Indication for Use

510(k) Number (if known): K080067

Device Name: iScience Interventional Canaloplasty Microcatheter

Indications for Use:

The iScience Interventional Canaloplasty Microcatheter is indicated for fluid infusion and aspiration during surgery.

The iScience Interventional Canaloplasty Microcatheter is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

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 CDRII, Office of Device Evaluation (ODE)



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

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