5.0 510(k) Summary

Submitter's Name: iScience Interventional Corporation
Submitter's Address: 4055 Campbell Avenue
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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
HMVX, 21 CFR 886.4350 Manual ophthalmic surgical instrument
Predicate Devices:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>510(k) Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>iScience Surgical Ophthalmic Microcannula</td>
<td>K041108</td>
</tr>
<tr>
<td>Endolight End Irrigating Endoilluminator</td>
<td>K970882</td>
</tr>
<tr>
<td>True Light End Irrigating Endoilluminator</td>
<td>K973293</td>
</tr>
</tbody>
</table>

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**

**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**

**Risk Management**

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.
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_   AND/OR   Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number _K080067_

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