K082871

510(k) Summary for the xact™ Injector

JUL - 9 2009

Name and Address of Sponsor

SIS Surgical Instrument Systems Ltd.
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2502 Port
Switzerland
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Name and Address of Manufacturer

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Name and Address of Official Correspondent

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Device Name

Device trade name: xact™ lens inserter
Common/Classification name: Intraocular Lens Folder and Injector

Classification, Panel and Product Code

Device Classification:	Class 1 (reserved), MSS
Reviewing Panel:	Ophthalmic Devices
Classification Code:	21 CFR Part 886.4300

Indications for Use

The xact™ foldable lens inserter (Model 6mm / 7mm) is a device intended to fold the Advanced Vision Science® 3-piece foldable lens and assisting in placing it into the capsular bag of the eye to replace the natural crystalline lens during normal small-incision cataract surgery. It provides a small tubular pathway in which the foldable lens can be placed into the eye with a continuous forward motion.

Device Description

The xact lens inserter (Model 6mm / 7mm) is a light weight plastic, single use, disposable device. It has a multi piece design, with an injector/handpiece unit and a separate cartridge.
The lens is delivered manually by action of the plunger. The final delivery is done by a screw-thread action. The final injection needs 2- 3 turns with screw thread until the final position of the plunger. The plunger allows for forward and backward action during delivery. The front end of the plunger is visible during delivery.
The lens inserter (Model 6mm / 7mm) is for both handed use: one hand for gripping and directing, while activating the plunger with the other. The plunger doesn't rotate inside the handpiece.
The lens is rolled rather than folded. The cartridge or rolling/folding mechanism locks in place on the handpiece.

Substantial Equivalence

The predicate devices which we are claiming substantial equivalence to are:

- Micro STAAR™ Injector MSI-P1 (K983129)
- the CeeOn™ EASYSERT (K002556)
- the MONARCH ® II IOL (K003768)

Performance data

The xact™ lens inserter (Model 6mm / 7mm) has been tested in vitro for proper functioning under various conditions of use. The results of these performance tests demonstrate that the xact™ lens inserter (Model 6mm / 7mm) reliably delivers the Advanced Vision Science® 3-piece foldable lens without impacting the optical performance, the dimensions or the cosmetic appearance of the lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SIS Surgical Instrument Systems Ltd.
c/o Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
5401 S. Cottonwood Court
Greenwood Village, CO 80121

JUL - 9 2009

Re: K082871
Trade Name: xact™ lens inserter system
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I (reserved)
Product Code: MSS
Dated: June 10, 2009
Received: June 11, 2009

Dear Mr. Walls:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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): K082871

Device Name: xact™ Lens Inserter

Indications: The xact™ foldable lens inserter is a device intended to fold the AVS 3-piece foldable lens, 6mm or 7mm optic, and assisting in placing it into the capsular bag of the eye to replace the natural crystalline lens during normal small-incision cataract surgery. It provides a small tubular pathway in which the foldable lens can be placed into the eye with a continuous forward motion.

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)

Kesia Alexander

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K082871