K070669

NOV - 1 2007

Medicel A.G.
510(k) Submission
IOL Injector Set
For Intraocular lenses
510(K) Summary
March 2, 2007

(1) Submitter Information

Name: Medicel AG

Address: Luchten 1262
Wolfhalden CH 9427
Switzerland

Telephone Number: 41-71-727-1057
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Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: March 6, 2007

(2) Name of Device:
Trade Name: IOL Injector Set
Common Name: Intraocular lens guide.
Classification Name: Folders and injectors, intraocular lens (IOL) (MSS, 886.4300)

(3) Equivalent legally-marketed devices:

K040837, Multiject injector, Medicel AG

(4) Description

The Medicel IOL Injector Set for intraocular lenses is intended to insert foldable intraocular whose labeling specifies this injector. The injector is available as reusable or single-use. The cartridge is single-use and is provided sterile..

(5) Intended Use

The Medicel IOL Injector Set for intraocular lenses is intended to insert foldable intraocular lenses for lenses specifying this injector set in their labeling.

(6) Technological characteristics

The device has two basic components: an injector (available either reusable or single use) and a disposable cartridge, sold sterile. The single-use injector is made of plastic and is sold sterile. The re-usable injector is made of titanium and can be autoclaved. The cartridge is made of lubricated polypropylene.

(b) Performance data

(1) Non-clinical tests

All contact materials have been tested for biocompatibility. The device was tested with each of the recommended intraocular lenses.

(2) Clinical tests

Not required

(3) Conclusions

The IOL Injector Set is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2007

Medicel AG
c/o George Myers, Sc.D
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K070669
Trade/Device Name: Medicel AG IOL Injector Set
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: KYB
Dated: October 12, 2007
Received: October 15, 2007

Dear Dr. Myers:

This letter corrects our substantially equivalent letter of November 1, 2007.

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 (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); 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,

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): K070669

Device Name: Medicel AG IOL Injector Set

Indications For Use: The Medicel IOL Injector Set and Cartridge for intraocular lenses is indicated for the insertion only of models of intraocular lenses that allow use of this injector in their approved labeling.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070669