K04-0837

JUN 17 2004

Medicel A.G.
510(k) Submission
MultiJect Reusable Injector
For Intraocular lenses
510(K) Summary
March 19, 2004

(1) Submitter Information

Name: Medicel AG

Address: Noellenstrasse 15a
CH - 9443Widnau
Switzerland

Telephone Number: 41-71-727-1050
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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: December 12, 2003??

(2) Name of Device:

Trade Name: MultiJect Injector for IOLs and MicroGlide Cartridge
Common Name: Intraocular lens guide.
Classification Name: Folders and injectors, intraocular lens (IOL) (MSS, 886.4300)

(3) Equivalent legally-marketed devices:

Allergan Phacoflex K961242
Alcon Monarch K003768

(4) Description

The Medicel MultiJect injector for intraocular lenses is intended to insert foldable intraocular lenses CeeOn 913A and Tecnis Z9000 made by Pharmacia when used in conjunction with the MicroGlide cartridge. The injector is reusable and can be autoclaved. The cartridge is single-use and is provided sterile. Two types of injectors are provided: a syringe type and a screw type. The MultiJect is designed to be used with the Pharmacia Tecnis Z9000 lenses and the Pharmacia CeeOn 913A lenses.

) Intended Use

e Medicel MultiJect injector for intraocular lenses is intended to insert foldable intraocular lenses CeeOn ›13A and Tecnis Z9000 made by Pharmacia when used in conjunction with the MicroGlide cartridge.

(6) Technological characteristics

The device has two components: a reusable injector and a disposable cartridge, sold sterile. The injector is made of titanium. The injector 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 MultiJect injector and MicroGlide cartridge are equivalent in safety and efficacy to the legally ›arketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Medicel AG
c/o Dr. George Myers
Medsys Inc.
377 Rt. 17S
Hasbrouck Heights, NJ 07604

Re: K040837
Trade/Device Name: MultiJet Injector and MicroGlide Cartridge
Regulation Number: 21 CFR 886.1850
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: March 23, 2004
Received: March 31, 2004

Dear Dr. Myers:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K040837

Device Name: **MultiJect Injector and MicroGlide Cartridge**

Indications for Use:

The Medicel MultiJect injector for intraocular lenses is indicated for the insertion of foldable intraocular lenses CeeOn 913A and Tecnis Z9000 made by Pharmacia when used in conjunction with the MicroGlide cartridge.

Prescription Use ____x_
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Don Calogero

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

510(k) Number K040837