OCT 8 - 2004

K 041019

MediSURG Ltd.
100 West Fornance Street
Norristown, PA 19401
Phone (610) 277-3937 Fax (610)277-7256

Premarket Notification [510(k)] Summary

Submitters name: Richard J. Fugo M.D., Ph.D.
Contact person: Richard J. Fugo M.D., Ph.D.
Date: March 8, 2004

Names:

D) Classification name: apparatus, cutting, radiofrequency, electrosurgical, battery powered.
E) Common/usual name: The Fugo Blade for Thermocauterization in Glaucoma
F) Proprietary Name: The Fugo Blade

Equivalence/ predicate device:

The Fugo Blade for anterior capsulotomy

- Description of device: included in prior section of this document.

Intended use of device:

HCFA Current Procedure Terminology (2004)

66155- Fistulization of sclera for glaucoma; thermocauterization with iridectomy.

Summary of the technological characteristics: as demonstrated in the prior section, the entire electronic system of Fugo Blade for thermocauterization in glaucoma is equivalent to the predicate system. The only difference in the two systems is the geometry of the disposable incision tips as delineated in detail above.

Determination of substantial equivalence: as stated, the electronic circuit is exactly the same for the two systems. Both systems produce the exact same electronic output signal characteristics. Therefore, both systems react

identically when placed in contact with tissue since they are the same electronic system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

Medisurg Ltd.
c/o Richard J. Fugo
100 West Fornance St.
The Fugo Building
Norristown, Pa 19401

Re: K041019
Trade/Device Name: The Fugo Blade for Glaucoma
Regulation Number: 21 CFR 886.4100
Regulation: Apparatus, Cutting, Radiofrequency, Electrosurgical, Battery-Powered
Regulatory Class: II
Product Code: NCR
Dated: September 29, 2004
Received: October 1, 2004

Dear Dr. Fugo:

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

Indications for Use

510(K) Number (if known): K041019

Device Name: Fugo Blade for Glaucoma

Indications for use: Sclerostomy for the treatment of primary open- angle glaucoma where maximum tolerated medical therapy and trabeculoplasty have failed.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

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

510(k) Number K041019