DEC 9 2005

K050933

MediSURG Ltd.
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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 28, 2005

Names:

A) Classification name: apparatus, cutting, radiofrequency, electrosurgical, battery powered.
B) Common/usual name: The Fugo Blade for Peripheral Iridotomy
C) Proprietary Name: The Fugo Blade

Equivalence/ predicate device:

A) Equivalence from an intended use standpoint: FDA cleared ND:Yag Laser for PI
B) Equivalence from a technological standpoint: The Fugo Blade for Capsulotomy

Intended use of device:

The Fugo Blade ® for peripheral iridotomy is indicated for intraocular creation of iridotomies.

807.92(a)(3)
Legally marketed device to which application is claiming equivalence:

1. Equivalence from an intended use standpoint: FDA cleared ND:Yag Laser for PI
2. Equivalence from a technological standpoint: The Fugo Blade for Capsulotomy

807.92(a)(4)
The Fugo Blade for PI is an electrosurgical device that is powered by the electromagnetic (EM) energy from flashlight size batteries. This energy is conditioned, tuned (9.8×10^{6} Hz) and focused on a thin, blunt cutting filament. Moreover, EM energy from flashlight size ("C" cell) batteries is fed into a proprietary electronic network system which is activated by the surgeon with an on/off switch. This electronic system is fed EM energy from the battery energy supply source then conditions, tunes (9.8×10^{6}) and focuses this EM energy into a 50-100 micron column of EM energy surrounding a blunt 100 micron diameter cutting filament at the end of the Fugo Blade hand piece. This column of EM energy is capable of reacting with iris tissue. This column of EM field energy causes the molecular bonds in the iris tissue which comes in contact with the EM field to ionize momentarily and thereby break apart, a condition that physicists refer to as a momentary "plasma formation". In this way, the molecular lattice of the iris is broken down, thereby creating a peripheral iridotomy.

807.92(a)(5)
The intended use of the device is to create an opening or iridotomy in iris tissue where lasers are not capable or desirable, thereby surgical intervention is required. The intended population is angle closure glaucoma or a clinical situation where the eye is at significant risk of angle closure. Such a group would also include intraocular lens (IOL) implants such as anterior chamber IOLs which have a high risk of precipitating angle closure. By placing a functional iridotomy in the iris, we have a channel which creates an equilibrium in the pressure of the anterior chamber and posterior chamber of the eye, thereby preventing or eliminating angle closure.

807.92(a)(6) – Summary of predicate technological characteristics
1. ND:Yag laser:
Random, incoherent electromagnetic (EM) energy from a halogen lamp is fed into a laser device called a resonant cavity which has a neodymium: yttrium – aluminum- garnet (YAG) crystal surrounded by a mirror reflection system on the cavity walls. This resonant cavity takes EM energy from a lamp source then conditions, tunes (2.8×10^{14}) and focuses this energy into a coherent column of EM energy that we call a "laser beam". This column EM energy is capable of reacting with iris tissue.

> "Optical breakdown, during interaction with the high powered laser with a very small area of tissue, in a short time causes the formation of "plasma", an area of totally ionized tissue": Reference- Klapper,RM. Q-switched neodymium: Yag laser iridotomy. Ophthalmology. 1984;91(9):1019.

In this way, the molecular lattice of the iris is broken down thereby creating a peripheral iridotomy.

2. The Fugo Blade for Iridotomy
Electromagnetic (EM) energy from flashlight size ("C" cell) batteries is fed into a proprietary network system. This electronic system takes EM energy from the batteries then conditions, tunes (9.8×10^6 Hz) and focuses this EM energy around a 100 micron diameter, blunt cutting filament at the end of the Fugo Blade hand piece. This column of EM energy is capable of reacting with iris tissue. This causes the molecular bonds in the iris tissue which comes in contact with the EM energy field to break and momentarily ionize, a condition that physicists refer to as a momentary "Plasma field". In this way, the molecular lattice of the iris is broken down, thereby creating a peripheral iridotomy.

3. Summary of Comparison between Fugo Blade for PI and ND:Yag laser for PI.
The systems both are powered by electrical source energy (battery DC current for the Fugo Blade and wall AC current for the laser). The systems both have an electronic network module which conditions, tunes (9.8×10^6 Hz for the Fugo Blade and 2.82×10^{14} Hz for the Yag laser), and focuses the output into a field of concentrated EM energy. The laser delivers a linear column of EM energy output whereas the Fugo Blade delivers a 50-100 micron thick EM field that coats or surrounds a blunt 100 micron diameter cutting filament. The systems both produce an EM field that is capable of reacting with iris tissue which indicates that both of the tuned output frequencies are in the absorption range of the iris tissue. The systems both produce optical molecular breakdown during interaction of the output EM field with a small area of iris tissue, and for a short time causes the tissue in contact with the output EM field to ionize and thereby create a momentary focus of "plasma", thereby creating a peripheral iridotomy. In conclusion, lasers are popularly known as operating with a coherent "light". A closer examination shows that light is a generalized description for the spectrum of EM radiation that stimulates the photoreceptors in the retina and thereby allows us to see. Yet, the Yag laser output is 1064 nanometers whereas the human eye cannot see EM radiation above 700 nanometers. Therefore, the EM field output of both the Fugo Blade for PI and the ND:Yag laser are both invisible to the human eye. Both the Fugo Blade and the ND:yag laser produce an EM field output, each at a different frequency. Likewise, the Yag laser produces a field output with a frequency different from an Argon laser and all other ophthalmic lasers.

807.92(b)(1) – Porcine eye models were employed to test preclinical assessment of performance data. The Fugo Blade was activated inside the anterior chamber of the porcine eye. Corneal endothelial imaging pre and post Fugo Blade activation demonstrated no significant degradation in endothelial cell count in the pre – activation and post – activation groups. The Fugo Blade also was examined for induced increase in intraocular heat. The study showed an increase of 0.11 °F per second of firing. The maximum time allowed for a Fugo Blade iridotomy is 5 seconds which would raise the temperature by 0.55°F. In conclusion, both endothelial cell count studies and heat generation studies support the safety of the Fugo Blade for PI.

807.92(b)(2)
From a technologic perspective, the Fugo Blade for PI was found to be equivalent to the Fugo Blade for capsulotomy (technologic predicate) since the 2 systems are the same

electronic system. From an intended use perspective, the Fugo Blade for PI was tested clinically for safety and effectiveness in 25 subjects with acute angle closure glaucoma and 25 subjects with phakic IOL insertion. These outcomes were compared to historical controls obtained from peer reviewed literature and were found to be equivalent.

807.92(b)(3)

The Fugo Blade for PI is as safe and as effective as the predicate devices. From a technologic perspective, the Fugo Blade for PI is the same electronic system as the Fugo Blade for capsulotomy (technologic predicate) and therefore has been shown to be equivalent to this predicate. From an intended use perspective, the Fugo Blade for PI has been shown to be equivalent in terms of safety and effectiveness for creating a PI to the ND:Yag for PI (intended use predicate). This is based on preclinical porcine studies on endothelial cell damage and anterior chamber heat generation. This is also based on clinical data in which 8 separate ND:Yag PI studies on angle closure patients published in Index Medicus peer reviewed journals were statistically compared to the Fugo Blade for PI study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

MediSURG Ltd.
% Richard J. Fugo, M.D., Ph.D.
100 West Fornance Street
Norristown, PA 19401

Re: K050933
Trade/Device Name: Fugo Blade for Peripheral Iridotomy, Model M300
Regulation Number: 21 CFR 886.4100
Regulation Name: Radiofrequency electrosurgical cautery apparatus
Regulatory Class: Class II
Product Code: NCR
Dated: November 28, 2005
Received: November 30, 2005

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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 : K050933

Device name: Fugo Blade for Peripheral Iridotomy, Model # M300

Indications for Use:

The Fugo Blade ® for Peripheral Iridotomy is indicated for intraocular creation of iridotomies.

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 CRDH, Office of Device Evaluatin (ODE)

Clay R. Butterman, DOED