K033390

NOV - 4 2003

510(k) Summary

SUBMITTER: MicroWorld Medical Instruments, Inc.
4640 Malat Street
Oakland, CA 94601 USA

CONTACT PERSON: Mr. Semyon Gambarin
Chief Executive Officer
Phone: (510) 534-7401
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DATE PREPARED: August 5, 2003

DEVICE TRADE NAME: COLIBRI Disposable Vitrectomy Cutter

COMMON/USUAL NAME: Vitrectomy Guillotine Cutter

CLASSIFICATION NAME: Vitreous Aspiration and Cutting Instrument

PREDICATE DEVICES: Bausch & Lomb Surgical MicroVit® Vitrectomy Cutter
M. Imonti and Associates Pro-Vit Vitrectomy Cutter
D.O.R.C. Disposable Pneumatic Vitrectome

DEVICE DESCRIPTION:

The COLIBRI Disposable Vitrectomy Cutter is a guillotine-style pneumatic handpiece for use during ophthalmic surgery. The main components of the device are the handle, diaphragm, inner spring, stainless steel inner and outer cutters, and attached tubing and connectors. The device provides cutting and aspiration functions during removal of vitreous and vitreal membranes in anterior and posterior segment surgeries. It is designed to be used with 20 psi and 30 psi ophthalmic surgical systems.

INDICATIONS FOR USE

The COLIBRI Disposable Vitrectomy Cutter is intended to be used for the removal of vitreous and vitreal membranes during ophthalmic surgery.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

This submission contains a comparison of the intended use and technical characteristics of the COLIBRI Disposable Vitrectomy Cutter to the predicate devices. The design and materials of the COLIBRI Disposable Vitrectomy Cutter are similar if not identical to those of ophthalmic guillotine cutters marketed today.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2003

MicroWorld Medical Instruments, Inc.
c/o Heinz-Joerg Steneberg
TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, CT 06470

Re: K033390
Trade/Device Name: COLIBRI Disposable Vitrectomy Cutter
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous aspiration and cutting instrument
Regulatory Class: Class II
Product Code: HQE
Dated: October 22, 2003
Received: October 23, 2003

Dear Mr. Steneberg:

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): K033390

Device Name:

COLIBRI Disposable Vitrectomy Cutter

Indications For Use:

The COLIBRI Disposable Vitrectomy Cutter is intended to be used for the removal of vitreous and vitreal membranes during ophthalmic surgery.

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 K033390

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)