K981155

AUG 14 1998

Hawken Industries Inc.
FlapMaker Microkeratome
510(k) Submission

510(k) Summary

(1) Submitter Information

Name: Hawken Industries Inc.

Address: 26650 Renaissance Pkwy.
Suite 3
Cleveland, Ohio 44128
U.S.A.

Telephone Number: 216-464-1119

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

Date Prepared: March 19, 1998

(2) Name of Device:

Trade Name: FlapMaker Disposable Microkeratome
Common Name: Disposable Microkeratome
Classification Name: Keratome, A-C powered

(3) Equivalent legally-marketed devices:

The predicate devices for the FlapMaker are Chiron Automatic Corneal Shaper, K941550, the Steinway Micro-Kerato-trephone K8436646, and the HANSA Automatic Corneal Shaper, K913697.

(4) Description

The device consists of a control console and disposable FLAPMAKER™ microkeratomes. The control console contains a suction pump, electronics, and flexible cables to actuate the disposable microkeratome. The basic system sold consists of the control unit, 20 disposable microkeratomes (sold sterile), 5 practice microkeratomes (not sold sterile), and interconnection equipment, including hoses, cables, and footpedals.

The FLAPMAKER™ microkeratome is a clear, automated, completely assembled, disposable microkeratome. It is made of biocompatible polycarbonate plastic and includes the blade made from surgical-grade steel. It is sold sterile and is for single use only. Each individual microkeratome is separately packaged in Tyvek, and is sterilized by gamma radiation.

The microkeratome is based upon the principle of the carpenter's plane. The blade, made from surgical stainless steel, oscillates at 12,500 rpm and is controlled by a unique patented flexible cable that is electronically driven. The blade extends a fixed distance from a transparent fixed plate and is at a 26° angle to the plate. Microkeratomes that create resection depths of 130 or 160 microns and resection diameters of 8.5mm and 10.5 mm are available. The microkeratome is mounted in a suction plate and is driven across the suction plate and protruding cornea at 6.8 mm/sec. by a patented flexible cable that is electrically actuated. The plastic suction ring, which supports the unit on the cornea, is made from biocompatible polycarbonate plastic.

The microkeratome itself is powered by two electric motors located in the control unit; motion is transmitted to the keratomes by mechanical transmission cables. The motors are UL approved. The central unit also supplies the suction. One cable transmits the motion to cause the blade to oscillate, and the other drives the device axially. As may be seen, there is no electricity transmitted to the keratome units. The microkeratome itself requires no assembly, but the connections to the central unit must be made before the operation. Separate units are available for different resection diameters and depths. The suction tubes are sold sterile one unit for a patient, and are sold with the microkeratomes.

(5) Intended Use

The FLAPMAKER™ is a disposable microkeratome that is intended to be used solely to make anterior lamellar corneal resections of preselected thickness and diameter. It is sold sterile and is for single-use only.

(6) Performance data

(1) Non-clinical tests

The FlapMaker has had electrical safety tests certified by the Canadian Standards Association. Plastic Materials in contact with tissue have been tested for biocompatibility. All motors are UL approved. Blades are surgical-grade stainless steel.

(2) Clinical tests

This device is identical to the predicate devices, except that the motors have been moved to a central unit and the energy is transmitted by cables. Since there is no change in technology or principles, a clinical test is not required.

(3) Conclusions

The FlapMaker microkeratome 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

AUG 14 1998

Hawken Industries
c/o George H. Myers, Sc.D
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K981155
Trade Name: FlapMaker Disposable Microkeratome
Regulatory Class: I
Product Code: 86 HNO
Dated: July 7, 1998
Received: July 8, 1998

Dear Dr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

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510(k) Number (if known): K981155

Device Name: Hawken FlapMaker Disposable Microkeratome

Indications for Use:

The FLAPMAKER™ is a disposable microkeratome that is intended to be used solely to make anterior lamellar corneal resections of preselected thickness and diameter. It is sold sterile and is for single-use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang, Scientific Reviewer

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981155

Prescription Use X **OR** **Over-the-Counter Use** _____

~~Use~~ /////

(Per 21 CFR 810.109)

(Optional Format 1-2-96)