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K993122

510K Summary
Medical Sterile Products
Disposable Microkeratome Blades

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FDA/CDRH/ODE/DHC

Food and Drug Administration
510K Document Mail Center
HFZ-401
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

09/11/99

RE: 510K Submission - Microkeratome Blades from:
Medical Sterile Products, Inc.
Road 413 Km. 0.2
Rincon, Puerto Rico 00677

Submitter's Name: Gary C. Dionne

To: Document Control Clerk

Medical Sterile Products, Inc. is requesting 510k approval for its disposable microkeratome blades. The microkeratome blades are manufactured either with a prefixed plastic post or have a slot/holes in the blade. The plastic post fits into a slot within the microkeratome instrument and the slot/holes in the blade are used to affix the blades to a stainless steel post on the microkeratome. The steel used for the blade in either configuration is the same, as well as the packaging and sterilization method. The blades are designed to be used in pre-existing, on the market, microkeratomes that presently use comparable disposable microkeratome blades.

Trade name :	MSP M/K BLADE
Common name:	microkeratome blade
Classification :	keratome, or/and blade, surgical saw, general and plastic surgery
Establishment Registration Number :	2618676

Performance Standard:

The Medical Sterile Products disposable microkeratome blades are similar in design and function to those blades marketed by:

Microspecialties, Inc.
16 Higgins Drive
Milford, CT 06460
510k Number : K980510 (Releasable 510k details attached)
K980508

Howard Instruments, Inc.
4749 Appletree Lane
Tuscaloosa, AL 35405
510k Number : K972727 (Releasable 510k details attached)

Med-Logics, Inc.
9327 Blackley Street
Temple City, CA 91780
510k Number : K962661 (Releasable 510k details attached)

Universal Refractive Instruments
B. Graczyk, Inc.
61 Brookside Drive
Glendale, IL (Promotional information attached)

Descriptive Comparison:

The Medical Sterile Products MSP M/K microkeratome blades are equivalent to those blades marketed by the above companies. The blades are designed to be used in existing microkeratome machines: Chiron, Moria, Med-Logics, SCMD.

Characteristics :

The microkeratome blades are single-use disposable. The blades are packaged in a plastic clamshell case and the case is packaged in a tyvek pouch. The blades are provided sterile.

Certification of Safety and Effectiveness:

When used according to the microkeratome manufacturers' instructions, there are no adverse safety indications for either of the blades. The blades are manufactured from surgical grade stainless steel. The blades will be sterilized gamma radiation.

Labeling:

The pouch will indicate Medical Sterile Products name, address, product identification, lot number, sterilization notes, disposable, and federal law requirements. Other companies could have the products relabeled with their company name.

Sterilization:

Gamma Radiation

Isomedix, Inc.
Division STERIS Contract Services
Vega Alta, Puerto Rico 00692

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2000

Mr. Gary Dionne
Director
Medical Sterile Products, Inc.
RD. 413, KM. 0.2
Rincon, PR 00677

Re: K993122
Trade Name: MSP M/K Blade
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370
Dated: February 24, 2000
Received: February 24, 2000

Dear Mr. Dionne:

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

510(k) Number (if known): K993122

Device Name: MSP/MK Blade

Indications For Use:

The MSP/MK Blade (#507-0028) is designed as a replacement blade for the Chiron Hansatome #507-0036-01 microkeratome for lamellar resection of the cornea.

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

ODE/DOD/DSDB

Concurrence of CDRH, Office of Device Evaluation (ODE)

D Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993122

(Optional Format 3-10-98)