JUL 14 1997

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K971538

Submitted By: David Downey
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Date Prepared:

Device Name

Proprietary Name: MENTOR® GEMINI™ HEMOSTATIC ERASER™

Common Name: Coagulator

Classification Name: Apparatus, Cautery, Radiofrequency, AC-Powered or Battery Powered

Indications For Use

The Mentor® Gemini™ Hemostatic Eraser™ is used to achieve episcleral and or intraocular hemostasis utilizing diathermy.

Substantial Equivalence

MENTOR® GEMINI™ HEMOSTATIC ERASER™ is similar in indications, design and features to MENTOR® WET-FIELD® HEMOSTATIC ERASER™ BIPOLAR INSTRUMENTS.

Device Description

The MENTOR® GEMINI™ HEMOSTATIC ERASER™ is a hand-held bipolar probe used for coagulation which consists of (a) a handle and (b) a disposable tip (electrode). The handle transfers RF energy to the disposable tip via a unique electrical contact system located in the internal cavity of the handle.

After a single use, the Tip is intended to be disposed of in a safe and cost effective manner. The handle is intended to be used 1-50 times before discarding.

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Substantial Equivalence Comparison

	MENTOR® WET-FIELD® HEMOSTATIC ERASER™	MENTOR® GEMINI™ HEMOSTATIC ERASER™
Indication	Replicates all functions for hemostasis, delivered through standard eraser products, for episcleral and intraocular diathermy.	Same
Design	Single use disposable, hand-held one-piece bipolar probe.	Hand-held bipolar probe consisting of (a) disposable tip (b) a reusable handle.
Material	Tube: Outer: 304 Stainless Steel Tubing. 18ga: .050 OD x .004" wall 20ga: .0355 OD x .004" wall 23ga: .0355 OD x .0025" wall	Same
	Center Electrode: . 18ga: 020" 302 Stainless Steel wire 20 and 23ga: .012" 302 Stainless Steel wire	Same
	Insulation: 18ga: Teflon extruded onto .020" Stainless Steel wire 20ga: Teflon extruded onto .012" Stainless Steel wire 23ga: Teflon shrink tubing, .002"-.003" wall	Same
	Connector Pin: 302 Stainless Steel	Same
Tip Interface	Permanently attached	Removable / Disposable
Cautery Tip Configuration	18, 20 and 23 gauge with various bend angles for user preference.	Same
Handle	ABS Plastic	6061-T6 Aluminum
Cautery Function	Hemostasis utilizing bipolar radio frequency	Same

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Handle	ABS Plastic	6061-T6 Aluminum
Cautery Function	Hemostasis utilizing bipolar radio frequency	Same
User Interface	Hand-held instrument that interfaces with the electrically isolated front panel of the MENTOR® WET-FIELD® Coagulator system via the MENTOR® BIPOLAR CABLE.	Same
Electrical Supply Source	MENTOR® WET-FIELD® Coagulator	Same
	Frequency: 445-455 Khz	Same
	Voltage: 400 Vpp ± 20V	Same
	Resistance (for erasers): >20meg OHMS	Same
Electrical Supply Connection	WET-FIELD® Bipolar Cable	Same
Sterilization Method	ETO	Tip: ETO
		Handle: Shipped non-sterile
		Steam sterilized by user.
Packaging	Tyvek pouch in box	Blister pack inside Tyvek pouch in box

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.

Submitter's Signature

4-18-97

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1997

Mr. David M. Downey
Director, Quality Assurance
and Regulatory Affairs
Mentor Ophthalmics, Inc.
3000 Longwater Drive
Norwell, MA 02061-1672

Re: K971538
Trade Name: Mentor Gemini
Hemostatic Eraser
Regulatory Class: II
Product Code: 86 HQO
Dated: April 18, 1997
Received: April 28, 1997

Dear Mr. Downey:

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 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

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): K971538

Device Name: Mentor® GEMINI™ HEMOSTATIC ERASER™

Indications For Use:

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(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971538

Prescription Use ✓
(Per 21 CFR 801.109)