



6174469
FEB 24 1998

510(k) SUMMARY

Date: February 3, 1998

Submitter: Donna A. Crawford,
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, CA 93111
Phone: 805-681-6000
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Trade or Proprietary Name: Mentor® Phacoemulsification SISstem Remote Control

Common or usual name: Remote Control

Classification name: Phacofragmentation system (accessory), 21 CFR 886.4670

Description and Intended Use of Device:

The Mentor® Phacoemulsification SISstem Remote Control is an accessory to the Mentor Phacoemulsification SISstem. It is a combination wireless and hard-wired hand-held device that allows the operator to control certain aspects of the Mentor Phacoemulsification SISstem's operation from a distance. When using the remote in a wireless mode, signals are transmitted to the console via IR (infrared) signals. When using the remote in the hard-wired mode, signals are transmitted to the console directly through the wire. The remote can be powered either by battery (when used in the wireless mode) or from the SISstem console itself (when the hard-wired mode is used).

The Mentor Phacoemulsification SISstem Remote Control is intended to be used by operating room personnel to control the main functions of the Mentor Phacoemulsification SISstem from a distance.

Substantial Equivalence:

The Mentor Phacoemulsification SISstem Remote Control has the same intended use and the same technological characteristics, and is therefore substantially equivalent to, the remote controls used with the Alcon Series 2000 Legacy

phacoemulsification system and the Chiron Vision Catalyst phacoemulsification system. The Alcon Legacy remote control and the Chiron Vision Catalyst remote control are full function, wireless, infrared remote controls. Please see the comparison table below.

COMPARISON TABLE

Feature	Alcon Legacy Remote Control 510(k) K952213	Chiron Vision Catalyst Remote Control 510(k) K925828	Mentor Phacoemulsification SIStem Remote Control
Wireless Infrared Remote Control	YES	YES	YES, also may be hard-wired
Controls I.V. Pole Height	YES	YES	YES
Memory Access	YES	?	YES
Mode Changes	YES	YES	YES
Performance Parameter Adjustments	YES	YES	YES
Hand motion sensor which initiates remote backlight for visibility in the dark	YES	?	NO
Optional sterile cover	YES	?	NO



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Ave.
Santa Barbara, Ca 93111

Re: K974469
Trade Name: Mentor Phacoemulsification SISstem Remote Control
Regulatory Class: II
Product Code: 86 HQC
Dated: November 24, 1997
Received: November 26, 1997

Dear Ms. Crawford:

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

INDICATIONS FOR USE STATEMENT

510(K) Number : K974469

Device Name:

Mentor® Phacoemulsification SIStem Remote Control

Indications for Use:

The Mentor® Phacoemulsification SIStem Remote Control is intended to be used by operating room personnel to control the main functions of the Mentor Phacoemulsification SIStem from a distance.

Prescription Use ✓
(Per 21 CFR 801.109)

Mareka L. Burke Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974469