MENTOR
CORPORATION

Executive Offices
5425 Hollister Avenue Santa Barbara, CA 93111 (805) 681-6000

JUL 17 199

510(k) SUMMARY

This 510(k) summary of 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: K970471

Submitted by: Clarke Scherff
Director Regulatory Affairs/Quality Assurance
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, CA 93111

Telephone: (805) 681-6000
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Date Prepared: February 6, 1997

Device Name

Proprietary Name: Mentor Ultrasound Assisted Tissue Removal System

Common Name: Ultrasonic Surgical Aspirator

Indication for Use

The Mentor Tissue Removal System indications for use are the ultrasonic liquefication and aspiration of soft tissue.

Device Description

The principles of operation and technology incorporated in the Mentor Tissue Removal System are equivalent to ultrasonic surgical aspirator systems which use ultrasonic energy to liquefy selected tissues. The Mentor TRS performs the functions of ultrasonic tissue liquefication, irrigation/infiltration and aspiration. The user interface consists of digital and bar displays of manually controlled parameters.

The system is controlled by the handpiece mounted switches or by traditional footpedal controls. The handpiece contains a piezoelectric transducer and connects by cable to the control module. The handpiece converts the electrical signal into ultrasonic mechanical vibrations which are amplified by the titanium cannula. The cannula may be used by itself or together with a stainless steel sheath which provides a path for irrigation. The irrigation and aspiration functions may be performed simultaneously or independently.

The Control Module/Ultrasonic Generator is designed to operate with the complete integrated Mentor Tissue Removal System or as a "stand alone" unit used in conjunction with existing aspiration and irrigation equipment.

Substantial Equivalence Claim

The principles of operation and technology incorporated in the Mentor Tissue Removal System are similar to other surgical devices with suction, ultrasound and irrigation functions which FDA has found to be substantially equivalent to pre-amendment devices as outlined in the following table:

Table 1

Manufacturer	Product	510(k) Number
Morwel Corporation	Ultra-Safe Ultrasonic Aspiration System	K962525
Valleylab	Valleylab CUSA System	K910696

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Clarke Scherff
Vice President Quality and Regulatory Assurance
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, California 93111

JUL 17 1997

Re: K970471
Trade Name: Mentor Ultrasound Assisted Tissue Removal System
Regulatory Class: II
Product Code: LFL
Dated: May 16, 1997
Received: May 19, 1997

Dear Mr. Scherff:

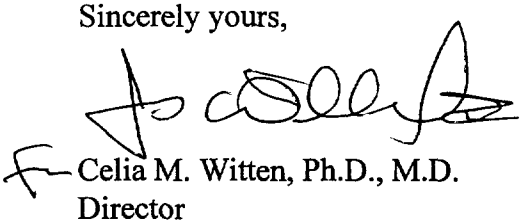
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970471

Device Name: MENTOR Ultrasound Assisted Tissue Removal System

Indications For Use:

The Mentor Ultrasound Assisted Tissue Removal System is indicated for use for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications.

(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 General Restorative Devices
510(k) Number K970471

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

(Optional Format 1-2-96)