

K973146

DEC - 4 1997

**510(k) SUMMARY
MENTOR ABSORBENT DRAPE**

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: K973146

Submitter/

Contact Person: Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Ave.
Santa Barbara, CA 93111

Telephone: (805) 681-6000
FAX: (805) 681-6004

Date Prepared: October 28, 1997

Device Name and Classification

Proprietary Name:	Mentor Absorbent Drape
Common/Classification Name:	Surgical Drape
Classification:	Class II per 21 CFR 878.4370

Manufacturer

Mentor
3000 Longwater Drive
Norwell, MA 02061

Substantial Equivalence Claim

The Mentor Absorbent Drape is equivalent to operating room towels and surgical drapes with absorbent properties, such as the American Threshold Disposable OR Towel and the Johnson & Johnson Sof-Wick Lap Pad.

Indications For Use

The Mentor Absorbent Drape is used to absorb fluids during surgical procedures.

Device Description

The Mentor Absorbent Drape measures 29 X 35 inches and is comprised of layered absorbent material between a permeable spunbond layer and a non-permeable layer. The device is packaged sterile for single use only.

Summary of Testing

The Mentor Absorbent Drape was tested for absorbency and found to absorb at least 100 cc per ft² of saline solution without leaking. The absorbent material did not leak out of the pad.

The Mentor Absorbent Drape was tested for strength under simulated clinical use conditions and was found to not rip, tear or separate during the testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Ophthalmics, Incorporated
5425 Hollister Avenue
Santa Hollister, California 93111

DEC - 4 1997

Re: K973146
Trade Name: Mentor Sterile Absorbent Drape
Regulatory Class: II
Product Code: KXX
Dated: October 30, 1997
Received: November 3, 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.

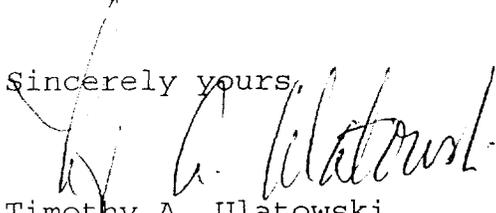
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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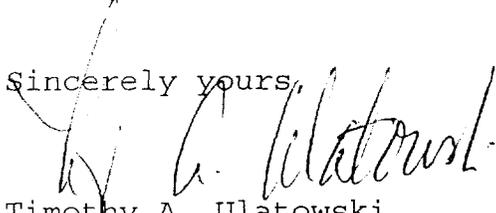
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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973146

Device Name: MENTOR Super Absorbent Drape

Indications For Use:

The Super Absorbent Drape is used to absorb fluids during surgical procedures.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K973146

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use X

(Optional Format 1-2-96)