K980050

FEB 27 1998

510(k) SUMMARY
MENTOR SKIN PROTECTION PAD

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: K980050.

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: January 5, 1998

Device Name and Classification

Proprietary Name:	Mentor Skin Protection Pad
Common Name:	Skin Protection Pad
Classification Name:	Unknown
Classification:	Unknown

Manufacturer

Mentor
3000 Longwater Drive
Norwell, MA 02061

Substantial Equivalence Claim

The Mentor Skin Protection Pad is substantially equivalent to the Guyuron Endoscopic Access Device manufactured by Applied Medical Technology, Inc.

Indications For Use

The Mentor Skin Protection Pad is used to protect the patient's skin from abrasion, frictional heat, or other minor damage that may be encountered during a surgical procedure. It is intended to adhere to the patient's skin around the incision site.

Device Description

The Skin Protection Pad will be available in two shapes: rectangular and semi-circular. It will consist of a pad substrate of rayon and polypropylene, a pad lining of polyethylene, a double-coated pressure sensitive adhesive, and a peel-away backing material with a release system. Three pads will be sealed in a TYVEK pouch. Twelve TYVEK pouches will be packaged in a shelf carton. The Skin Protection Pad is sterile and single-use only.

Summary of Testing

The Mentor Skin Protection Pad was tested for biocompatibility as follows. A sensitization study in the guinea pig was performed using the closed patch method. Under conditions of this study, the Mentor Skin Protection Pad showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Also, a skin irritation study was performed in the rabbit. No irritation was observed on the skin of the rabbits. Lastly, a cytotoxicity test using the ISO agarose overlay method in the L-929 mouse fibroblast cell line was performed. The Mentor Skin Protection Pad showed no evidence of causing cell lysis or toxicity greater than a USP grade of 2 (mild reactivity).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

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

Re: K980050
Trade Name: Mentor Skin Protection Pad
Regulatory Class: II
Product Code: GCJ
Dated: January 5, 1998
Received: January 6, 1998

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 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) 594-4595. 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,

for 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):_____

Device Name: MENTOR Skin Protection Pad

Indications For Use:

The Mentor Skin Protection Pad is used to protect the patient's skin from abrasion, frictional heat, or other minor damage that may be encountered during a surgical procedure.

(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 K980050

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)