

JAN 30 1998

510(k) Premarket Notification Submission
3M™ Universal Electrosurgical Pad 9135 & 9165

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K974279

510(k) Summary
3M™ Universal Electrosurgical Pad
9135 & 9165

Name and address of Device Manufacturer submitting 510(k) Notification:

3M
Medical Products Group
3M Health Care
3M Center
St. Paul, MN 55144-1000

Regulatory Correspondent of Device Manufacturer:

Linda Johnsen
Regulatory Affairs Specialist
3M Health Care
Building 275-3E-08
St. Paul, MN 55144-1000
612 737-4376

Date Summary was prepared: November 12, 1997

Name of Devices:

3M™ Universal Electrosurgical Pad, with cord (Catalog 9135)
3M™ Universal Electrosurgical Pad, Split with cord (Catalog 9165)

Classification: Electrosurgical Cutting and Coagulation Device and Accessories, Class II per 21 CFR 878.4400

Indications for Use:

3M™ Universal Electrosurgical Pads 9135 & 9165 are designed to work with most electrosurgical units (ESUs) for virtually every surgical application where electrosurgery is utilized to provide a safe return path for electrosurgical current. Solid Universal Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split style Universal Electrosurgical Pad is for use with ESUs that have a CQMS (i.e. REM, ARM, NESSY etc.). 3M™ Universal Electrosurgical Pads are designed to be used on any patient where full skin contact and a suitable placement site can be obtained. There are no patient weight restrictions for use of this product. Use of this product for unintended applications could lead to an unsafe condition.

Description of the Devices: 3M™ Universal Electrosurgical Pads, 9135 & 9165 have a green shaded coating technology that more uniformly distributes electrosurgical RF current over the whole conductive surface of the pad. The more uniform distribution technology and square shape permits universal orientation of the pad at a suitable placement site. The pad has a maximum temperature rise that is similar to pads up to 33% larger in conductor surface area. The entire surface of the conductive area is covered with a soft, conformable hydro-gel conductive adhesive. The pad also has a non-conductive border adhesive surrounding the entire conductive surface area to isolate the conductive area from surgical fluids. These pads include a disposable pre-attached cord.

Safety and Efficacy:

Biocompatibility:

The biological safety of selected components of the 3M™ Universal Electrosurgical Pads has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Tests were selected on the basis of Part-1 of ISO 10993-1, "Biological Evaluation of Medical Devices".

ANSI/AAMI Performance Testing:

The 3M™ Universal Electrosurgical Pad, Split with cord (9165) meets 5.2.3.1 Maximum Safe Temperature Rise, 5.2.3.2 Electrode Contact Impedance and 5.2.8.2.2 Contact Quality Monitor of the ANSI/AAMI HF18-1993 Voluntary Standard for Electrosurgical Devices.

The 3M™ Universal Electrosurgical Pad, with cord (9135) meets 5.2.3.1 Maximum Safe Temperature Rise, 5.2.3.2 Electrode Contact Impedance and 5.2.3.3 Electrode Adherence c) Fluid Tolerance Test, of the ANSI/AAMI HF18-1993 Voluntary Standard for Electrosurgical Devices.

The 3M™ Universal Electrosurgical Pad, with cord meets 5.2.5.1 Dielectric Withstand 60 Hz and 5.2.5.2 High Frequency Leakage Current of the ANSI/AAMI HF18-1993 Voluntary Standard for Electrosurgical Devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Ms. Linda Johnsen
Regulatory Affairs Specialist
3M Health Care
3M Center, Building 275-3E-08
St. Paul, Minnesota 55144-1000

Re: K974279
Trade Name: 3M™ Universal Electrosurgical Pad, with cord (Catalog 9135)
3M™ Universal Electrosurgical Pad, Split with cord (Catalog 9165)
Regulatory Class: II
Product Code: GEI
Dated: November 12, 1997
Received: November 14, 1997

Dear Ms. Johnsen:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

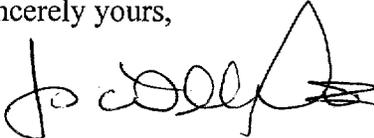
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



fr 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): K974279

Device Name: 3M™ Universal Electrosurgical Pad, with cord (Catalog Number 9135) and 3M™ Universal Electrosurgical Pad, Split with cord (Catalog Number 9165)

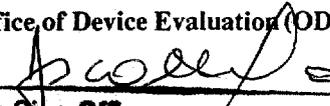
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These electrodes will include the precaution statement: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

(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 K974279

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the Counter Use _____

(Optional Format 1-2-96)