K974553 FEB - 3 19

510(k) Summary
3M™ Universal Electrosurgical Pad
9130 & 9160

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, (Catalog 9130)
3M™ Universal Electrosurgical Pad, Split (Catalog 9160)

Classification:

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

Indications for Use:

3M™ Universal Electrosurgical Pads are designed to work with most electrosurgical units (ESU'S) 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.). The 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, 9130 & 9160 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 25% 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 area to isolate the conductive area from surgical fluids.

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".

AAMI Performance Testing:

The 3M™ Universal Electrosurgical Pad, (9130) meets the ANSI/AAMI 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 of the ANSI/AAMI HF18-1993 Voluntary Standards for Electrosurgical Devices.

The 3M™ Universal Electrosurgical Pad, Spilt (9160) 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/Maximum Safe Temperature Rise of the ANSI/AAMI HF18-1993 Voluntary Standards for Electrosurgical Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 1998

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

Re: K974553
Trade Name: 3M™ Universal Electrosurgical Pad, (Catalog 9130)
3M™ Universal Electrosurgical Pad, Split (Catalog 9160)
Regulatory Class: II
Product Code: GEI
Dated: November 12, 1997
Received: November 17, 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.

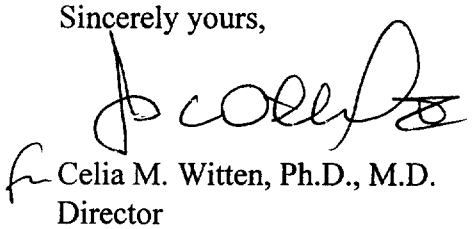
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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): K974553

Device Name: 3M™ Universal Electrosurgical Pad, (Catalog Number 9130)
3M™ Universal Electrosurgical Pad, Split (Catalog Number 9160)

Indications For Use:

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These electrodes will include the precaution statement: USA Federal 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974553