

OCT 21 1997

Two Ludlow Park Drive  
P.O. Box 297  
Chicopee, MA 01021-0297  
413-593-6400

**Ludlow Technical Products**

**510 (k) SUMMARY**

Electrosurgical Dispersive Electrodes  
Pediatic Dual and Single Element Pads  
Ludlow Technical Products  
Two Ludlow Park Drive  
Chicopee, MA 01022

K973110

Ludlow Technical Products considers their pediatic dual and single element ESD electrodes to be safe and effective for use in monopolar electro-surgery when used according to the intended procedures as related in the instructions accompanying the product. The function of the Ludlow Technical Products pediatic ESD electrodes is to complete the electrosurgical circuit between the patient, the active electrode, and the generator. The instruction for use insert as well as the pouch labeling contain the necessary warnings per the AAMI standard section 4.1.4.2 "Electrodes intended for use on Infants".

The safety issues of the device were evaluated to the ANSI/AAMI specification HF 18-1993 whereby this standard was issued to "help insure safe and effective use of electrosurgical devices". The ANSI/AAMI standard HF 18-1993 covers all facets of electrosurgical devices. The Ludlow Technical Products Pediatic ESD electrodes were tested according to section 4.2.3 "Dispersive Electrodes", which covers Maximum Safe Temperature Rise, Electrode Contact Impedance, Electrode Adherence, and Packaging/Shelf life; also, section 4.2.5 which covers "Operating Conditions". In each of the test areas listed, the Ludlow Technical Products Pediatic dispersive electrode met the requirements of the ANSI/AAMI HF 18-1993 standard. These results are on file at Ludlow Technical Products.

The Ludlow Technical Products Pediatic electrode was also tested successfully to the ISO - 10993, Biological Evaluation of Medical Devices Part I : Evaluation & Testing.

The Ludlow Technical Products Pediatic ESD electrode is substantially equivalent to products existing the marketplace. The Valleylab E7510 Infant REM Polyhesive II is a Disposable Patient Return Electrode to which we have drawn the comparison. The Ludlow Technical Products pediatic electrode functions the same as the Valleylab E7510 Infant pad. The products are the same in their construction using conductive adhesive hydrogel along with a foil/polyester conductor plate and a foam insulation backing.

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

M. Beth Rice

M. Beth Rice

Product Manager

A **tyco** INTERNATIONAL LTD. COMPANY

8/5/97

Date



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Patrick A. Malia  
Manager of Quality Assurance  
Ludlow Technical Products  
Two Ludlow Park Drive, PO Box 297  
Chicopee, Massachusetts 01021-0297

1997

OCT 21 1997

Re: K973110  
Trade Name: Disposable Dispersive Electrode, Pediatric, Dual and Single Element,  
Corded and Non-Corded  
Regulatory Class: II  
Product Code: GEI  
Dated: August 5, 1997  
Received: August 20, 1997

Dear Mr. Malia:

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 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

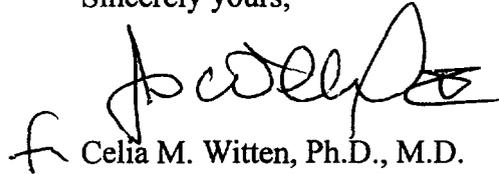
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devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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



INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K973110

Device Name: \_\_\_\_\_

Indications For Use:

The ProCam Medical Pediatric Dispersive Electrode is indicated for use in monopolar electrosurgical applications as a non-sterile, disposable device, for single patient use, only. It is intended to disperse the current as it is removed from the patient during the electrosurgical process. By connecting to the electrosurgical generator, via the pre-attached cable or re-useable cable, the circuit is completed causing successful cutting or coagulation in the patient. This electrode is intended for use in electrosurgery on pediatric patients weighing 25 lbs. or less and with the generator power settings less than 150 watts. The Pediatric Dispersive Electrode is not indicated for use for high-powered procedures such as transurethral resection (TUR). The device will work with any standard generator.

(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

K973110

Prescription Use X

OR

Over-The-Counter Use

(Per 21 CFR 801.109)