K965245

UTAH MEDICAL PRODUCTS INC.

510(k) Summary

JUL 2 1997

December 27, 1996

Trade Name:	TBD
Common Name:	Irrigation Aspiration Coagulation Electrode
Classification:	Electrosurgical Cutting and Coagulation Device and Accessories, 21 CFR 878.4400

The Irrigation/Aspiration/Coagulation Electrodes (ICE) are substantially equivalent to Utah Medical Products, Inc.'s ACE-311 and ACE-511 Aspiration/Coagulation Electrodes (K955093) used for fluid aspiration and coagulation, combined with the irrigation feature of the MegaDyne Medical Products, Inc.'s All-In-One Hand Control #0055 (K922002).

The device consists of a stainless steel spherical ball electrode attached to an ULTEM® irrigation and aspiration head that has PVC irrigation and aspiration tubes. The posterior end of the electrode shaft fits snugly into a standard electrosurgical pen which is connected to an electrosurgical generator that has been cleared for marketing by the FDA. The irrigation tube has a PVC female Luer fitting for connection to a fluid source and the aspiration tube has an ABS suction adapter for connection to a standard vacuum suction system.

The ICE-311 and ICE-511, are indicated for electrosurgical fulguration (coagulation) of the uterine cervix as part of the procedure called Loop Excision of the Transformation Zone (LETZ®), or other loop electrosurgery procedures where simultaneous electrosurgical fulguration and small-volume fluid irrigation and/or aspiration is needed. When used according to the instructions for use, in the hands of a trained user, the device provides an effective tool for allaying excessive bleeding by fulgurating and desiccating the surface of wounds produced during surgical procedures. The irrigation and aspiration features allow the user to flush the surface of the wound and aspirate fluids and blood that would interfere with cauterization of the surgical wound. The Aspiration and Coagulation functions of the ICE electrodes are identical to the functions of the UMP ACE electrodes. The irrigation function of the ICE electrodes is substantially equivalent to the function of the MMP #0055, although that device is intended for use in laparoscopic procedures.

The technological characteristics of the ICE electrodes are substantially equivalent to the UMP ACE electrodes and the MMP #0055 hand control. There are differences in the materials used, however, they are all biocompatible materials. The MMP #0055 has flow control valves incorporated into it, whereas, the UMP ICE requires external control of the irrigation fluid and the aspiration vacuum.

Laboratory tests of the UMP ICE and the MMP #0055 have demonstrated that the irrigation fluid flow differs by less than 4% and that the aspiration capability differs by less than 8%. The coagulation capabilities of the UMP ICE and the UMP ACE are equivalent since they are based on the same UMP DBL electrodes.

Kevin L. Cornwell
President & CEO

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UTAH MEDICAL PRODUCTS INC. • 7043 South 300 West • Midvale, Utah 84047-1048 • 801/566-1200 • FAX#801/566-2062

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1997

Mr. John W. Smith
Quality Assurance Manager
Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047-1048

Re: K965245
Disposable Irrigation/Aspiration/Coagulation Electrode
Dated: April 21, 1997
Received: April 23, 1997
Regulatory class: II
21 CFR §884.4120/Product code: 78 HGI

Dear Mr. Smith:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K965245

Device Name: Irrigation/Aspiration/Coagulation Electrode

Indications For Use:

Indications

The Irrigation/Aspiration/Coagulation Electrodes, ICE-311 and ICE-511, are indicated for electrosurgical fulguration (coagulation) of the uterine cervix as part of the procedure called Loop Excision of the Transformation Zone (LETZ®), or other loop electrosurgery procedures where simultaneous electrosurgical fulguration and small-volume fluid irrigation and/or aspiration is needed.

Contraindications

The ICE-311 and ICE-511 should not be used where loop electrosurgery is contraindicated. Examples of contraindications for LETZ are:

- Pregnancy
- Acute or active inflammation of the cervix, endometrium, fallopian tube, ovary or peritoneum (cervicitis, endometritis, tubo-ovarian inflammatory disease or pelvic inflammatory disease)
- Invasive cancer that is visible on examination
- Known or suspected cervical changes secondary to DES (diethylstilbestrol) uterine exposure.

Consult the electrosurgery unit (ESU) operation manual for details.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert B. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K965245

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

(Optional Format 1-2-96)