

JUN 22 1998

K 981724

**SAFETY AND EFFECTIVENESS SUMMARY  
Medtrex O.R.Pro 300™ Electrosurgical Generator**

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

Medtrex Incorporated  
14 Inverness Drive East,  
Building B, Suites 116-120  
Englewood, Colorado 80112

**Regulatory Correspondent of Device Manufacturer:**

William J. Bowers  
Medtrex Incorporated  
14 Inverness Drive East  
Building B Suites 116-120  
Englewood, Colorado 80112  
Phone: (303)790-2032  
FAX: (303)790-0302

**Date Summary was prepared:**

May 11, 1998

**Name of the device:**

O.R.Pro 300™ Electrosurgical Generator

**Classification:**

Electrosurgical cutting and coagulation device and accessories. Class II per 21CFR 878.4400

**Indications for Use:**

The O. R. Pro 300™ Electrosurgical Generator is a general purpose solid state generator used to supply the RF signals to electrosurgical handpieces used on soft tissues where a wide range of tissue types, patient conditions and load impedances are encountered.

**Description of the device:**

The OR Pro 300™ is a full powered electrosurgical generator with separate monopolar and bipolar sections. The monopolar section is designed for cutting and coagulation outputs, is intended for use with a patient return electrode, and is a floating, isolated output. The bipolar section incorporates a separate output from the monopolar output and has independently controlled power. The Bipolar section

is a floating isolated output and is intended to be used with bipolar instruments.

AC power mains is applied to the generator from a detachable line cord. This power mains voltage is converted to a DC voltage and applied to a single RF amplifier. An RF amplifier utilizes power MOSFETs to convert the DC voltage into a RF energy that is suitable for electrosurgical procedures. The generator is activated by either handswitching or footswitching active accessories.

Three different types of CUTTING, Pure, Blend 1 and Blend 2, can be selected by the push buttons on the front panel.

Two different types of COAG, Pinpoint and Spray, can also be selected on the front panel. In addition, BIPOLAR COAG is provided through the bipolar output jacks.

**Substantial Equivalence:**

The Medtrex O.R. Pro 300 Electrosurgical Generator is substantially equivalent to the following two legally marketed electrosurgical generators:

Valley Laboratories Inc.  
Boulder, Colorado 80301  
Force FX™ Electrosurgical Generator  
510(k) K944602, cleared 6/5/95

Aspen Surgical Systems  
Div of ConMed /Corporation  
311 Broad Street  
Utica, NY 13501  
Excalibur*Plus* Electrosurgical Generator  
510(k) K953007 Cleared 8/21/95

**Safety and Efficacy:**

The O.R.Pro has been tested to all applicable requirements of AAMI HF18-R-10/93 – American National Standard for Electrosurgical Devices. The O.R.Pro300 met all the applicable requirements of the Standard. The requirements of the Standard that were not applied to the O.R. Pro were those associated with the electrosurgical pencil and return pad. These devices were cleared for marketing by separate submissions listed under Accessories.



JUN 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medtrex Incorporated  
c/o Mr. William E. McKay  
President  
RCMDI  
9712 South Altamont Drive  
Sandy, Utah 84092

Re: K981724  
Trade Name: O.R. Pro 300™ Electrosurgical Generator  
Regulatory Class: II  
Product Code: GEI  
Dated: May 13, 1998  
Received: May 15, 1998

Dear Mr. McKay:

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.

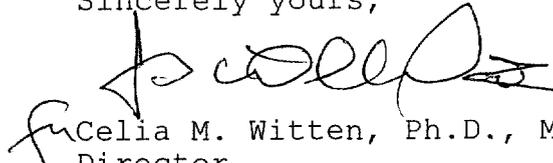
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. William E. McKay

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

510(k) Number (if known): ~~Not yet assigned~~ K981724

Device Name: O. R. Pro 300™ Electrosurgical Generator

Indications For Use:

The O. R. Pro 300™ Electrosurgical Generator is a general purpose solid state generator used to supply the RF signals to electrosurgical handpieces used on soft tissues where a wide range of tissue types, patient conditions and load impedances are encountered.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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

K981724