K972267

SEP 14 1999

SUMMARY OF EQUIVALENCY OF SAFETY AND EFFECTIVENESS

HELICA 'TC', VALLEY LAB. APEC AND ERBE APC 300

HELICA 'TC'	VALLEY LAB. APEC	ERBE APC 300
INTENDED USE:		
Laparoscopic, Endoscopic, and open surgical procedures where Monopolar electrosurgery is normally used.	Same	Endoscopy
Not intended for use on patients with right to left cardiac shunting.	Same	Unknown
PRODUCT DESCRIPTION:		
The 'TC' is a microprocessor controlled Helium Thermal Coagulator. Working at 2 to 33 watts of power with Helium gas flows of 1 to 5 liters/minute depending on procedure and probe.	Use several generators Ranging from 40 to 120 Watts and Argon gas flows From 0.5 to 16 liters/minute .	APC 300 generator Not specified Argon gas flows From 0.1 to 9 liters /minute.
The 'TC' automatically works with all of the flexible disposable probes. Models T, C, D, E, R, and S. (Size range 2.5mm to 4mm x 60 mm to 310mm)	Uses a number of hand sets Depending on procedure.	Uses 3 specified Probes depending Type of operation.
In all cases probe is activated (foot control) in the gas-enhanced mode, A Helium plasma is created between the probe and the target tissue. This mode permits the user to coagulate tissue in a more controlled manner than with standard fulguration and the flow of inert gas produces the following additional beneficial effects: (1) The presence of inert gas at surgical site inhibits combustion with other gases (e.g., oxygen, nitrogen, etc.)	Does the same using Argon gas . Has both hand and foot controls.	Does the same Using Argon gas.

And the gas jet pushes any residual smoke or water vapor away from the site, thereby improving visibility, and (2) The gas jet pushes blood out of the way which significantly reduces the coagulation of blood on the surface of the tissue and provides the surgeon with improved visibility at surgical site.		
SAFETY and PERFORMANCE		
The Helica 'TC' due to its design and the use of Helium needs only very low gas pressure (does not exceed 1.5 psi at probe tip) and very low wattage to achieve excellent results.	Needs more gas pressure And power due to Argon Being a heavier gas and to Design of the generator Hand set.	Same.
Published studies show that gas-enhanced electrosurgery is safe effective.	Same.	Same.
BIOCOMPATABILITY		
Selection of materials meet all known standards.	Same.	Same.
ELECTRICAL		
Meets or exceeds all applicable sections of, IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety, IEC 601-2-2 (1991), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment, and ANSI /AAMI HF18 (1993), Electrosurgical Devices.	Same.	Same.
SUMMARY NUMBERS	K924918, K931028, K942579, K954229, K962690	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

John B. Webb, Ph.D.
CEO
Tenerco, Inc.
1020 West Bay Avenue
Newport Beach, California 92661

Re: K972267
Trade Name: Helica TC (Thermal Coagulator)
Regulatory Class: II
Product Code: GEI
Dated: August 25, 1999
Received: August 26, 1999

Dear Dr. Webb:

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) 594-4595. 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

Statement of Indications for Use

510 (k) Number: K972267

Device Name: Helica TC (Thermal Coagulator)

Indications for Use: The device is a helium gas electrosurgical coagulator for use in all soft tissue surgery--laparoscopic, endoscopic, and open.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972267

Prescription Use X OR Over-the-Counter Use____
(Per 21 CFR 801.109)