MAR 31 2000

K 99 3412

Revised 01/21/2000

J. 510(k) Summary

January 21, 2000

Company:	Everest Medical Corporation 13755 First Avenue North Minneapolis, MN 55441 Tel. No. (612) 473-6262 FAX. No. (612) 473-6465
Contact:	Frederick G. Mades Quality Assurance/Regulatory Affairs Manager
Common/Usual Name:	Electrosurgical Instruments
Classification Name:	Electrosurgical Cutting and Coagulation Device And Accessories (21 CFR 878.4400)
Proprietary Name:	BiTx Probe

The devices are Class II medical devices. The BiTx devices are similar in construction and in component materials when compared to laparoscopic and thorascopic devices. In particular they are similar to the BiLAP Probes submitted in 510(k) no's. K904993, K945975 and K955001. The devices are tubular instruments, either 3mm or 5mm in diameter, with shaft lengths of 15cm. The intended use of the device is to electrosurgically cut and coagulate soft tissue during the performance of arthroscopic procedures. The energy source, Bipolar Electrosurgical Energy, is the same energy type as used for the previously cleared laparoscopic and thorascopic devices. The devices are constructed from the same materials and are processed similarly to the predicate devices. The device incorporates a return electrode on the distal end of the shaft eliminating the need for a return pad.

In conclusion, as the design, materials of construction, function and intended use of the BiTx device is similar to that of the predicate devices currently marketed in the United States, Everest Medical believes that no new issues of safety and effectiveness are raised and that this device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2000

Mr. Frederick G. Mades
Quality Assurance/Regulatory Affairs Manager
Everest Medical Corporation
13755 First Avenue North
Minneapolis, Minnesota 55441

Re: K993412
Trade Name: BiTx Probes
Regulatory Class: II
Product Code: GEI
Dated: January 21, 2000
Received: January 24, 2000

Dear Mr. Mades:

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,

for 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): K993412

DEVICE NAME: BITX PROBES

INDICATIONS FOR USE:

Arthroscopic electrosurgical cutting and coagulation of soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative D

510(k) Number K993412