

K981272



AUG 24 1998

**ETD, INC.**  
ELECTRO-THERAPEUTIC  
DEVICES INC.

**510(k) SUMMARY.**

**Name of device:**

ADDIQUIP disposable Acupuncture needles. K981272.  
Product code: MQX.  
Classification panel : 80.

Submitter's Name; Electro Therapeutic Devices Inc.  
570 Hood Road, ste.14,  
Markham, Ont.  
Canada L3R 4G7.  
tel. no. (905) 475 8344.  
fax no. 905 475 5143.

Date: 28th July 1998.

Manufacturer's Name & Address:  
WU XIHOU ZHAI M.E. Factory,  
WUXI, JIANG SHU, China.

Comparison to a legally marketed device:  
**CARBO(k961339)** acupuncture needles from China.  
Enclosed photocopy of their packaging.

**CARBO**

Stainless steel disposable  
acupuncture needles.

Made in China.

Sterilized by ETO.

CAUTION LABEL:Federal law  
restricts this device to sale  
by or on the order of qualified  
practitioners of acupuncture  
asdetermined by the states.

Size description of needles  
both in metric and imperial  
ie. 0.22 x 40mm and 1"ga.34.

Sterile expiry date & lot no.  
Packing: 100 needles per box.  
Each needle in sterile,blister  
pack.

**ADDIQUIP.**

Stainless steel disposable  
acupuncture needles.

Made in China

Sterilized by Ethylene Oxide

Similar

Similar

Similar



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 24 1998

Mr. K. C. Choong  
President  
Electro-Therapeutic Devices, Incorporated  
570 Hood Road, Suite 14  
Markham, Ontario  
CANADA L3R4G7

Re: K981272  
Trade Name: ADDIQUIP Disposable Acupuncture Needles  
Regulatory Class: II  
Product Code: MQX  
Dated: July 28, 1998  
Received: July 30, 1998

Dear Mr. K. C. Choong:

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 legally marketed predicate 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 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 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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html>".

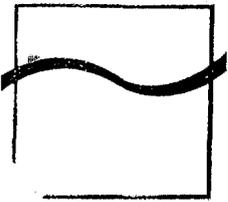
Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K981272



**ETD INC.**  
ELECTRO-THERAPEUTIC  
DEVICES INC.

**INDICATION for USE statement.**

ADDIQUIP disposable acupuncture needles: K981272.

"To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States."

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

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

(Optional Format 1-2-96)

---

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number \_\_\_\_\_