

3/4/99

K983671

T.C.M. Supply Corp.

12490 Central Ave., Ste.#221 Chino, CA 91710 (909) 628-9698

SUMMARY

Acupuncture needles is defined as a device intended to pierce the skin in the practice of acupuncture by qualified practitioner of acupuncture as determined by the States.

Acupuncture needles have been used for the general practice of acupuncture in the United States for over 30 years. Since this time, we are not aware of any serious or life threatening accident involving acupuncture needles.

Acupuncture needles, which were sold through commercial interstate distribution prior to May 28, 1976, were non-sterile, reusable acupuncture needles. Acupuncture needles, which were currently being marketed through interstate distribution, offer greater safety since they are sterile, single use only acupuncture needles.

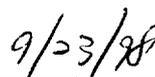
The subject of this 510(k) application - the Natural Brand acupuncture needles - is sterile, single use acupuncture needles. The Natural Brand acupuncture needle meets the general specifications and criteria for an acupuncture needle and is effective for the practice of acupuncture.

The Natural Brand acupuncture needle was manufactured in China and has been imported and sold through interstate commerce in the USA since 1985 under the FDA labeling restriction of: "Caution: Investigational device limited by U.S. law to investigational use". Since 1985, no accidents or device failure claims have been reported as a result of using the Natural Brand acupuncture needle.

In conclusion, based on the information provided with this 510(k) application, the Natural Brand acupuncture needle meets the criteria for 510(k) acceptance. The Natural Brand needle is equivalent to acupuncture needles which were in commercial distribution prior to May 28, 1976. Also, the Natural Brand needle is equivalent to other acupuncture needles, which are currently being sold through interstate commerce.



William Hung Lee, President



Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1999

Ms. Catherine Arquillano
TCM Supply Corporation
12490 Central Avenue, Suite 221
Chino, California 91710

Re: K983671
Trade Name: Natural Branch Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: January 22, 1999
Received: January 29 1999

Dear Ms. Arquillano

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

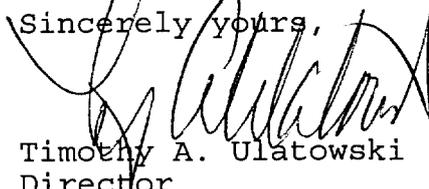
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (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,



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

Enclosure

K983671

510(k) Number (if known): _____

Device Name: Acupuncture Needles

Indications For Use:

The acupuncture needles are devices used by licensed practitioners which are intended 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)

Patricia Cicchetti
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K983671

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____