K972658

Dong Bang, U.S.A.

Premarket Notification
510(k) Summary

OCT 17 1997

Submitted by:

Sue Kim (General manager)
Dong Bang USA
13640 Imperial Hwy #01
Santa Fe Spring, CA 90670
Office: 562-407-7435
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Device Trade Name: Magi Acupuncture Needle
Device Generic Name: Acupuncture Needle
Classification: Class II.
Product Code: MQX

Device Description: The Magi acupuncture needle is a sterile surgical stainless steel, single use only acupuncture needle. The Magi acupuncture needle meets the general specifications and criteria for an acupuncture needle and is effective for the practice of acupuncture.

The Magi acupuncture needle was first manufactured in China in 1992 by the Dong Bang Medical Instrument Co., LTD and has been imported and sold through interstate commerce in the USA since 1992 under the FDA labeling restrictions , that states: "Caution: Investigational device limited by U.S. Law to investigational use". Since 1992, no accident or device failure claims have been reported as a result of using the Magi acupuncture needle.

Intended Use: Acupuncture needles are defined as devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

MAGI®
THE FUTURE BIOTECH

Substantial Equivalence: Magi acupuncture needles are currently sold in the USA under numerous propriety names by other medical device companies. Also, the Dong Bang needle is equivalent to other legally marketed acupuncture needles which are currently being sold through interstate commerce.

Sue Kim General Manager

7-11-97.
Date

Medical, Acupuncture, Dental
Health Food, Herbal Formulas
Export/Import/Distribute

13640-01 Imperial Hwy.
Santa Fe Springs, CA 90670
(310) 407-7433
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Sue Kim
General Manager
Dong Bang, U.S.A.
13640 East Imperial Highway, #1
Santa Fe Springs, California 90670

OCT 17 1997

Re: K972658
Trade Name: Magi Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: September 2, 1997
Received: September 9, 1997

Dear Ms. Kim:

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) 594-4618. 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

K972658

510(k) Number (if known): _____

Device Name: **Magi Acupuncture Needles** 9/02/97

Indications For Use:

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)

Vicki Hibbard for Patricia Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972658

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)