5/4/99

K990328

MorningStar, DongBang Acupuncture U.S.A., Inc.

PRE-MARKET NOTIFICATION 510(K) SUMMARY
{As Requested by 21 CFR 807. 929 (c)}

Submitter: Ae-Hoe Kwon (President of Morning Star/Staff of Dong Bang Medical Co., LTD)
Morning Star, Dong Bang Acupuncture U.S.A., Inc.
1429 Lyndon St. S. Pasadena, CA 91030-3381
Tel: 626) 403-5959, Fax: 626) 403-0128, E-mail: DBCacup@aol.com

Issued Date: January 28, 1999

Trade name: DBC, Dong Bang Acupuncture Needles, 510(k) Number: **K990328**
Common name: Acupuncture Needles Classification: II
Classification name: Needle, Acupuncture, Single Use Product code: MQX
The Legally Marketed Device: DBC Acupuncture Needles, **510(k) K963300**

Description of Device:
The acupuncture needles manufactured by Dong Bang Medical Co., LTD in Korea have been imported and sold through interstate commerce in the USA since 1988 under the FDA labeling restrictions of "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the State." The subject of this 510(k) application, "DBC, Dong Bang Acupuncture Needles," is a γ-ray or EOG sterile, non-pyrogen, stainless, and single use only acupuncture needle and is identical to the DBC brand needles, 510(k) K963300. The DBC, Dong Bang acupuncture needles have various type (pipe or spring) needle handles, and are packaged by bulk or single sealed blister.

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." Single use only acupuncture needles have been used for "the general practice of acupuncture" in the United States. The proposed DBC, Dong Bang Acupuncture Needles have the same intended use as the DBC Acupuncture Needles which are currently being marketed through interstate distribution (K963300), because the two devices are manufactured by a same company.

Safety, Effectiveness, and Fundamental Scientific Technology:
Since 1988, no accidents or device failure claims have been reported as a result of using the acupuncture needles supplied by Dong Bang Medical Co., LTD in the U.S.A. Sterile, stainless, single use only acupuncture needles offer greater safety. The proposed DBC, Dong Bang acupuncture needles meet the general specifications and criterion for acupuncture needles and are effective for the practice of acupuncture. The differences in trade and distributor names in labeling do not alter safety, effectiveness, or device's fundamental scientific technology.

Substantial Equivalence:
In conclusion, based on the information provided with this 510(k) application, the DBC, Dong Bang brand acupuncture needle meets the criterion for 510 (k) acceptance. The subject of this application is the same safe and effective DBC acupuncture needle which has been legally marketed in commercial distribution. For this DBC, Dong Bang acupuncture needle is identical to the legally marketed DBC acupuncture needle, 510(k) K963300 submitted by an other importer (Lhasa Medical, Inc.) of Dong Bang Medical Co., LTD. The differences in trade and distributor names in labeling do not affect the device's intended use or alter the device's fundamental scientific technology.

Ae-Hoe Kwon, contact person Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 4 1999

Mr. Ae-Hoe Kwon
President
Morning Star, Dong Bang Acupuncture U.S.A., Incorporated
1429 Lyndon Street
South Pasadena, California 91030-3381

Re: K990328
Trade Name: DBC, Dong Bang Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: March 4, 1999
Received: March 8, 1999

Dear Mr. Ae-Hoe Kwon

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 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

K990328

510(K) NUMBER (IF KNOWN): K990328
DEVICE NAME: DBC DONGBANG ACUPUNCTURE NEEDLES

INDICATIONS FOR USE

DBC Dongbang Acupuncture Needles have been used for "the general practice of acupuncture without any other specific use or treatment" in the United States. These single-use-only acupuncture needles 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-CONTINE ON ANOTHER PAGE IF NEEDED.)

Concurrence ~~of CDRH, Office of Device Evaluation~~ (ODE)

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

510(k) Number K990328

Prescription Use ✓, OR Over-The-Counter-Use_____.
(Per 21 CFR 801.109) (Optional Format 1-2)