

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

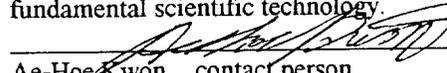
Trade name: DBC, Dong Bang Acupuncture Needles, 510(k) Number: K990328
Common name: Acupuncture Needles Classification: II
Classification name: Needle, Acupuncture, Single Use Product code: MQX
The Legally Marketed Device: DBC Acupuncture Needles, 510(k) K963300

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.

 1/28/99
Ae-Hoe Kwon, contact person Date

1429 Lyndon St.
S. Pasadena,
CA 91030-3381
T: 626) 403-5959
F: 403-0128
DBCacup@aol.com



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.

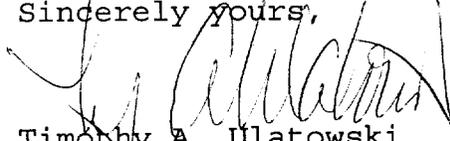
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Ae-Hoe Kwon

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-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of ~~CDRH~~ Office of Device Evaluation (ODE)
(Division Sign-Off) *Patricia Cuente*
Division of Dental, Infection Control,
and General Hospital Devices

Prescription Use OR *K990328* Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2)



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
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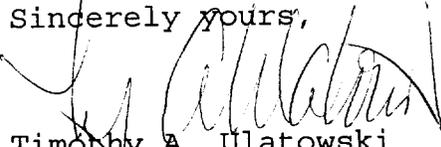
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Sincerely yours,



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

Enclosure

2

K990328

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

INDICATIONS FOR USE

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

Concurrence of ~~CDRH~~ Office of Device Evaluation (ODE)
(Division Sign-Off) *Fabrizio Cuente*
Division of Dental, Infection Control,
and General Hospital Devices

Prescription Use 510(k) Number *K990328* OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Date: 4/30/99
Reviewer(s) - Name(s) Irene Navarre

Subject: 510(k) Number K990328/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 3/2/99.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

80/II / MQX / 880.5580

Review: Patricia Cicente
(Branch Chief)

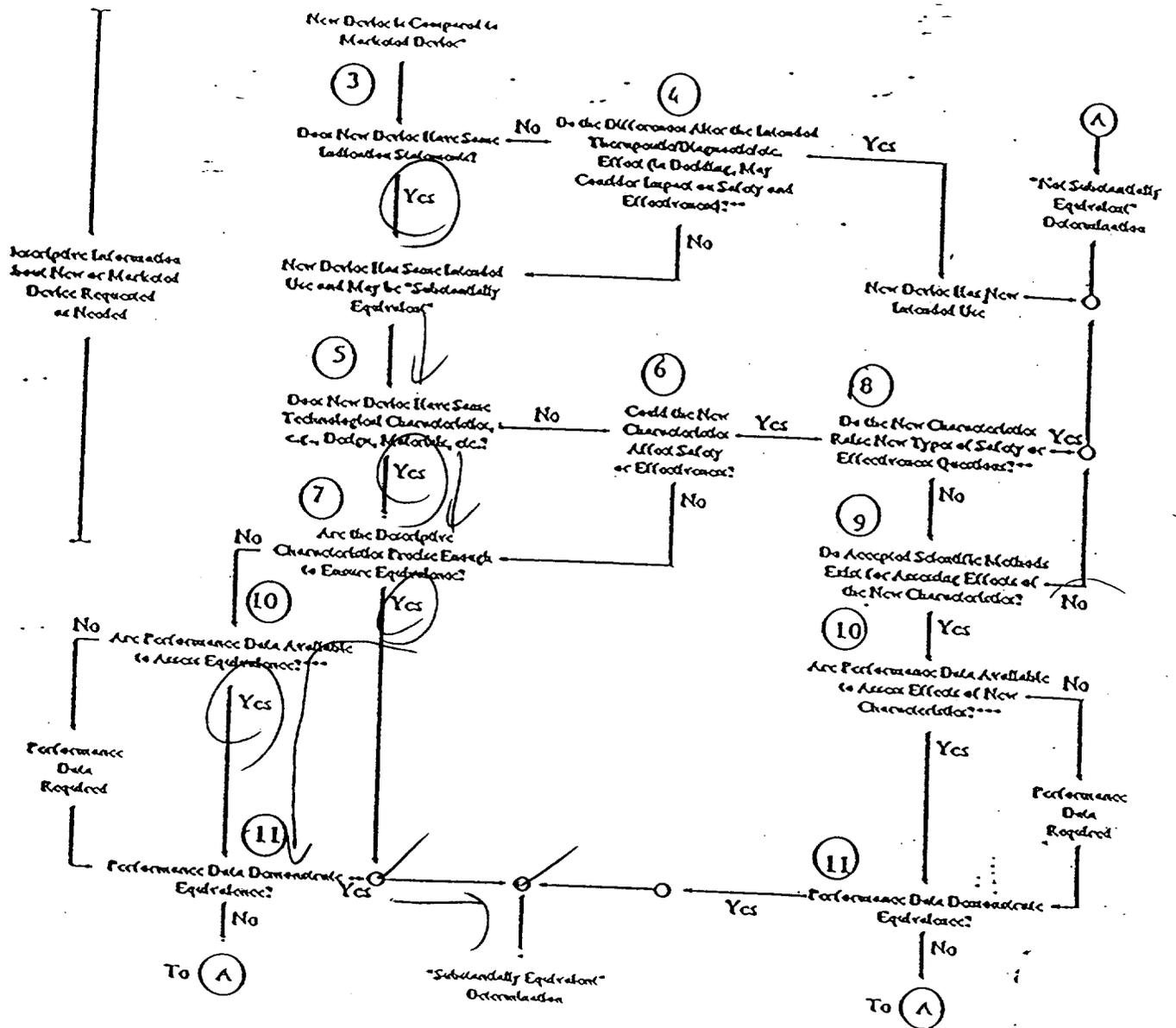
6403
(Branch Code)

3/3/99
(Date)

Final Review: _____
(Division Director)

5/3/99
(Date)

S10(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



S10(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the S10(k), other S10(k)s, the Center's classification files, or the literature.

MEMO TO THE RECORD
510 (K) REVIEW

K990328

Date: April 30, 1999
From: Irene Naveau

Office: HFZ-480
Division: DDIGD/GHDB

COMPANY NAME: Morning Star, Dong Bang Acupuncture U.S.A., Inc.
DEVICE NAME: DBC, Dong Bang Acupuncture Needles

"SUBSTANTIAL EQUIVALENCE (SE) DECISION-MAKING DOCUMENTATION"

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The DBC, Dong Bang Acupuncture Needles are sterile, single use, acupuncture needles for general purpose use. They consist of stainless steel (SUS 304) pine leaf shaped needles which are mechanically attached to one of two types of brass and nickel chromed handles. These acupuncture needles are available with single or bulk packaged pipe handles or with a spring type handle. No adhesive bonding is used. A silicone lubricant is used on each needle. Sizes will vary from 0.16x7mm to 0.70x160mm. An insertion tube of polypropylene is included with each needle.

2. INTENDED USE: To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long term): No
- C. Is the device sterile? Yes; The acupuncture needles will be sterilized with either ethylene or gamma irradiation. For those needles sterilized with EtO, the SAL is 10^{-6} and residue levels are: EtO: 15ppm; EC: 21ppm, and EG: 217ppm. Pyrogen method is the rabbit test. For those needles sterilized with gamma irradiation, the validation method is ISO1137, the SAL is 10^{-6} , the dosage is 25kGy (EN552), and the pyrogen testing is by rabbit test.

Packaging: For single pipe: polypropylene and PET sterilized paper; for pipe and spring handled acupuncture needles, PET and LLDPE

- D. Is the device for single use? Yes
- E. Is the device for prescription use? Yes
If yes, is prescription labeling included? See labeling.
- F. Is the device for home use or portable? Not indicated for home use.

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- G. Does the device contain drug or biological product as a component? No
- H. Is the device a kit? No
- I. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): N/A
- J. Device (s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: DBC Acupuncture Needle, Lhasa Medical, Inc., K963300.
- K. Submission provides comparative specification a Yes
comparative in vitro data b No
performance data c Yes
animal testing d No
clinical testing e No
biocompatibility testing f No

- L. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The DBC, Don Bang Acupuncture Needles are identical to the predicate device, DBC Acupuncture Needles in intended use, materials. Labeling, package inserts, and specifications are the same. The only differences are the trade names, distributor guidance, and color in the packaging.

Functional testing included: (b)(4)

(b)(4)

A biocompatibility certification statement was provided.

The labeling is adequate for this device. Labeling was revised and the appropriate caution and prescription statements were added. A bulk packaging statement was also included where appropriate.

Based on the information provided in this 510k, I ascertained that this device is substantially equivalent to the predicate device by Lhasa Medical, Inc. No new issues of safety and effectiveness exist for this device.

- M. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based?
Yes

N. RECOMMENDATION:

I believe that this device is equivalent to: 80 MQX

Classification should be based on: Acupuncture Needle

880.5580 Class: II

Irene Naveau 4/30/99
Irene Naveau

2

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K990328

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: DBC, Dong Bang Acupuncture Needle

Product To Which Compared (510(K) Number If Known): DBC Acupuncture Needle, Lhasa Medical, Inc., K963300.

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

1. Intended Use: To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
2. Device Description: Refer to SE Memo dated April 30, 1999.

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K990328/A3

Ae-Hoe Kwon
MorningStar, DongBang 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

April 7, 1999

FEDERAL BUREAU OF INVESTIGATION
APR 15 1 25 PM '99
FBI/DOJ

Attention: Irene Naveau
FDA/CDRH
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Ref: 510(k) Number: K990328.
Device Name: DBC, Dong Bang Acupuncture Needles

Dear Irene Naveau,

I am sending you a revised application which contains 3 copies for the proposed labeling.
Please, if you have any question, feel free to call me.
Thank you very much.

Sincerely yours,


Ae-Hoe Kwon

5/3/0

10



TO REMOVE
NEEDLE
FROM
PACKAGE
DO NOT
OPEN

SINGLE HANDLE

Caution: Do not use
if the seal is broken or
damaged by improper use. Gas
sterilized by Ethylene Oxide Gas.

STERILE ACUPUNCTURE NEEDLES

Size: **025x40 mm**
Lot No: **90103**
Exp Date:

Dr. M. Thomas, D.O.
Acupuncture USA, Inc.
100 East 10th Street, Suite 200
New York, NY 10003
Tel: (212) 677-1111
www.acupunctureusa.com



TO REMOVE
NEEDLE
FROM
PACKAGE
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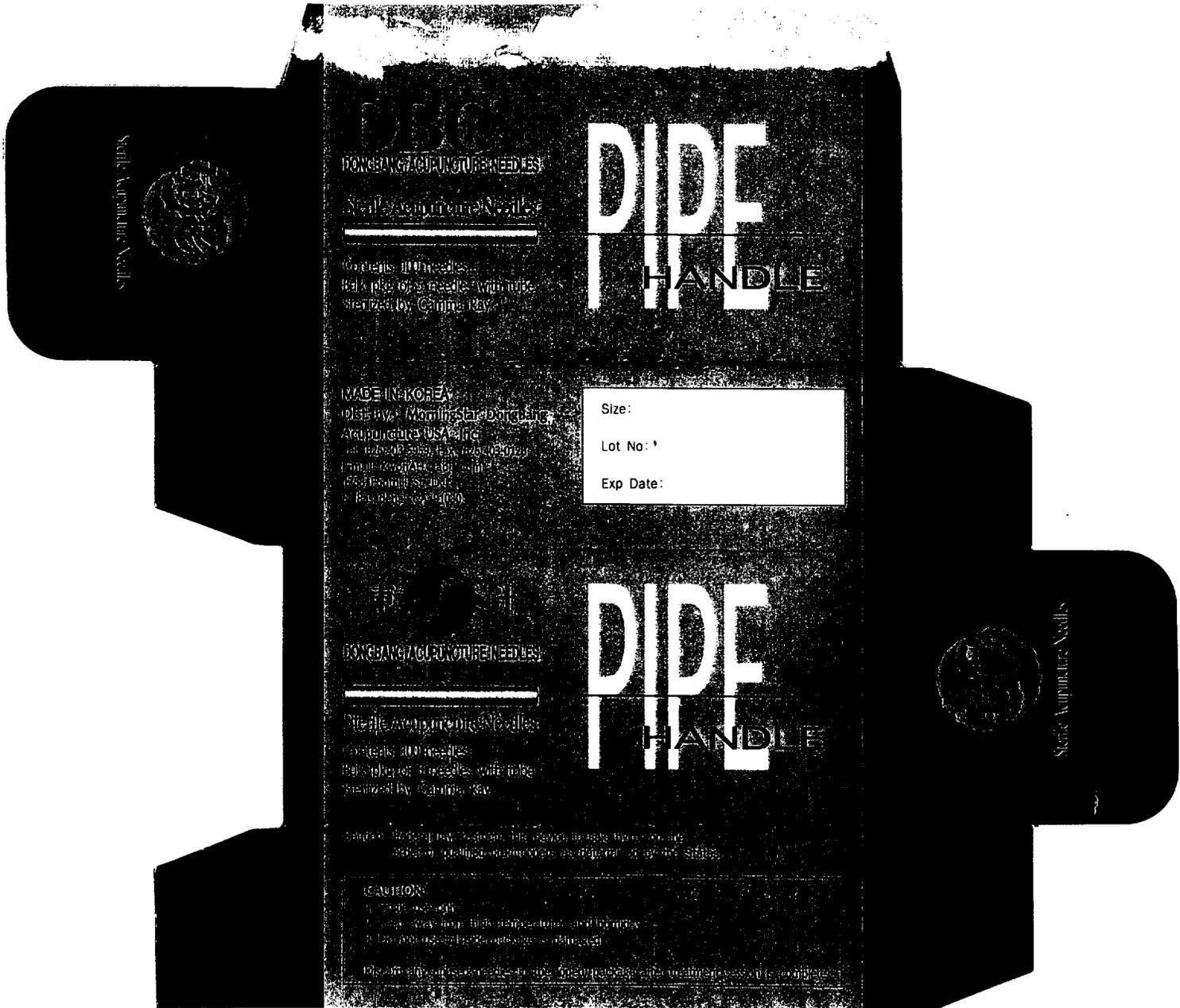
SINGLE HANDLE

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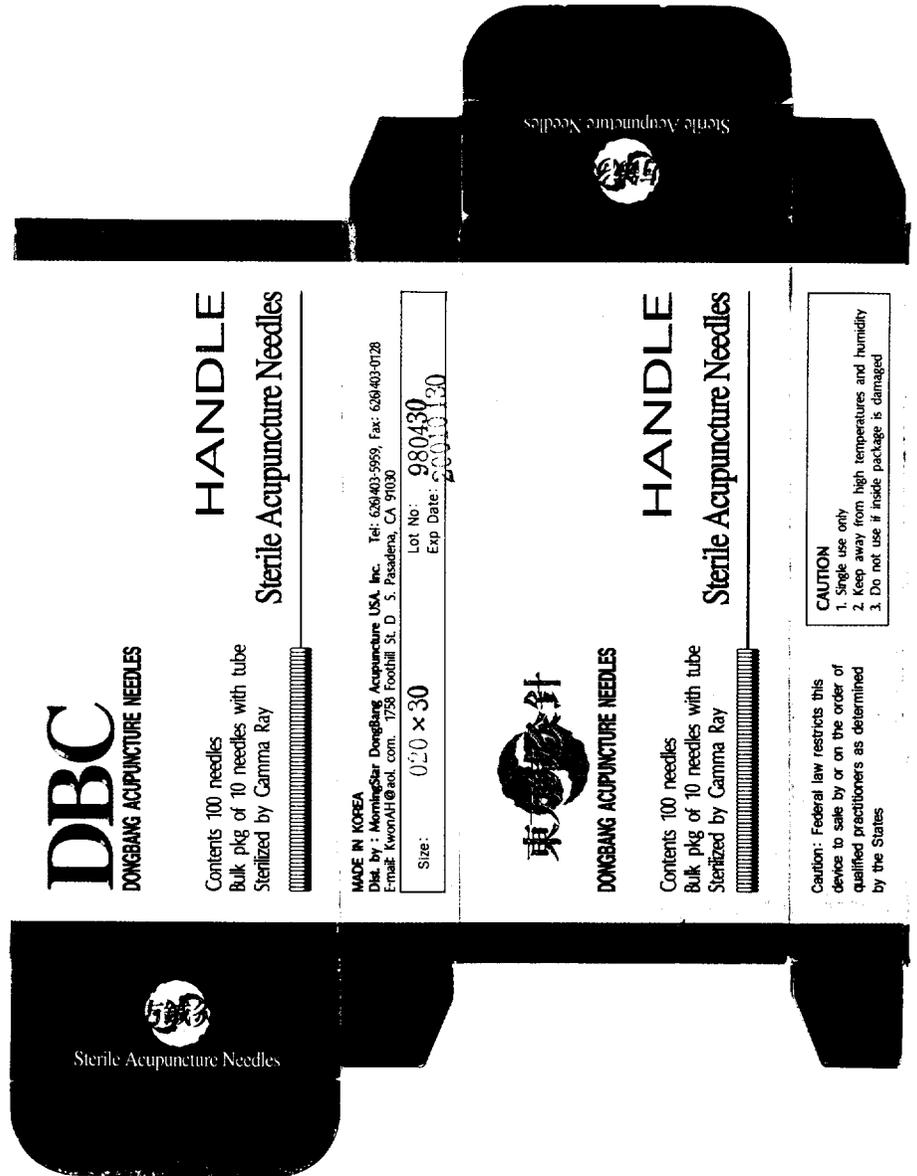
STERILE ACUPUNCTURE NEEDLES

CAUTION
1. Single use only
2. Keep away from high
temperatures and humidity
3. Do not use if inside package is
damaged

Sterile Acupuncture Needles



12



DBC
DONGBANG ACUPUNCTURE NEEDLES

Contents 100 needles
Bulk pkg of 10 needles with tube
Sterilized by Gamma Ray

HANDLE
Sterile Acupuncture Needles

MADE IN KOREA
Dist. by : MemingStar DongBANG Acupuncture USA, Inc. Tel: 626/403-9999, Fax: 626/403-0728
Email: kwonAH@aol.com, 1758 Foothill St, D. S. Pasadena, CA 91030

Size: 0.20 x 30
Lot No: 980430
Exp Date: 2003.12.0



DONGBANG ACUPUNCTURE NEEDLES

Contents 100 needles
Bulk pkg of 10 needles with tube
Sterilized by Gamma Ray

HANDLE
Sterile Acupuncture Needles

CAUTION
1. Single use only
2. Keep away from high temperatures and humidity
3. Do not use if inside package is damaged

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States

Sterile Acupuncture Needles

Sterile Acupuncture Needles



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510(K) NOTIFICATION

1. Reason and Purpose for Submission:

This is a revised application with reference to a new 510(k) number: K990328 for Marketing through a new trade name, DBC, Dong Bang Acupuncture Needles.

2. Legally Marketed Device:

DBC Acupuncture Needles 510(k) No. K963300 submitted by Lhasa Medical, Inc. DBC Acupuncture Needle is identical to the subject of this application and is manufactured by Dong Bang Medical Co. LTD (DBC).

3. Device Classification Name:

Needle, Acupuncture, Single Use

4. Device Trade Name:

DBC, Dong Bang Acupuncture Needles

5. Applicant:

Morning Star, Dong Bang Acupuncture U.S.A., Inc.
(A Regional Office of Dong Bang Medical Co., LTD)
1429 Lyndon St. S. Pasadena, CA 91030-3381
Tel: (626) 403-5959
Fax: (626) 403-0128

6. Contact:

Ae-Hoe Kwon

7. Product Code:

MQX

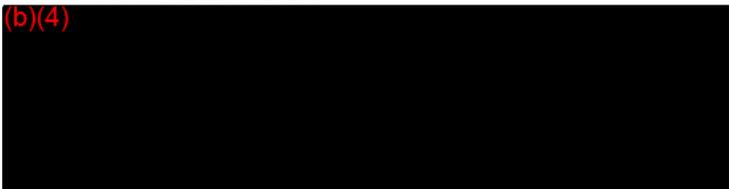
8. Class:

Type II

9. Medical Specialty (panel):

General Hospital (21 CFR Part 880)

10. Manufacturer:

(b)(4)


APR 15 1 25 PM '99
FDA/CDRH/OCE/DMC

Date Submitted: April 7, 1999

(Ae-Hoe Kwon)



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Dong Bang Acupuncture Needles Co., or DBC, is the same company. DBC is the brand name and abbreviation of Dong Bang Acupuncture Needles Co., and DBC has been patented to Keun-Sik Kim (president) by the Korean Patent Bureau since 1994. The company name has been changed to Dong Bang Medical Co., LTD. I will from here on out use Dong Bang Medical Co., LTD.

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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

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{As Requested by 21 CFR 807. 929 (c)}

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Issued Date: April 7, 1999
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510(k) Number: **K990328**
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Classification name: Needle, Acupuncture, Single Use
Product Code: MQX
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Description of Device:

DBC Dongbang Acupuncture Needles are acupuncture needles, manufactured by Dong Bang Medical Co., LTD in Korea, which have been imported and sold through interstate commerce in the USA ever since 1988. The subject of this 510(k) application **DBC, Dong Bang Acupuncture Needles** is a new device: it 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 Dongbang Acupuncture Needles** come in both types: pipe-handle and spring-handle. They are also packaged in both bulk and single-sealed blister package.

Intended Use:

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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.

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(Ae-Hoe Kwon) _____



Date: 04/07/1999

lb

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as “regional office staff in charge,” importer and the US designated agent of Dong Bang Medical Co., LTD (DBC), I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Ae-Hoe Kwon

04/07/1999

(Dated)

K

(Pre-market Notification [510(k)] Number)

17

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-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____, OR
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2)

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1. GENERAL INFORMATION

1-1. The Name of Device

1-1-1 Trade Name: **DBC, Dong Bang Acupuncture Needles**

1-1-2 Common or Usual Name: **Acupuncture Needles**

1-1-3 Classification Name: **Needle, Acupuncture, Single Use**

1-2 The Class of Device: **Class II**

1-3 Medical Specialty (panel): **General Hospital** (21 CFR Part 880)

1-4 Product Code No: **MQX**

1-5 The Establishment Name and Registration Number

1-5-1 Manufacture Name: **Dong Bang Medical Co., LTD (DBC)**

* FDA Registration No: **8040810** (since 1988)

* Device Listing No: **B 008479**

* Address of Manufacturer:

(b)(4)

1-5-2 Applicant: **Morning Star, Dong Bang Acupuncture U.S.A., Inc.:**

Regional Office/the Sole US Agent designated by DBC

* FDA Registration Form Operation and owner ID: (b)(4)

* LA Regional Registration Form No: (b)(4)

1-6 Purpose of Submission

Since the current 510(k) K963300 belongs to the specific importer, the manufacturer or other importers are unable to use the current 510(k). For marketing a new trade name, DBC, Dong Bang Acupuncture Needles through a new importer, a new 510(k) number different from a legally marketed DBC is called for.

- This package is a revised application with reference to a **New 510(k) Number: K990328**. All old application documents must be replaced by this new one.

1-7 A Legally Marketed Predicate Device: **DBC Acupuncture Needles, 510(k) Number. K963300**.

This 510(k) number was submitted by Lhasa Medical, Inc. and the acupuncture needles are manufactured by Dong Bang Medical Co., LTD (DBC). The subject of this application is identical with the DBC acupuncture needles as a predicate device for substantial equivalence.

2. DESCRIPTION OF THE PROPOSED DEVICE

2-1 Statement of 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.” Acupuncture needles have been used for “the general practice of acupuncture” in the United States. The DBC, Dong Bang acupuncture needles have only the intended use and indication for use in labeling for the “general practice of acupuncture,” without any other specific use or treatment.

2-2 Device Specifications

2-2-1 Physical Specifications

DBC, Dong Bang acupuncture needles have no visible defects in acupuncture needle body finishing under the magnification of 100 times. Their tips are pine leaf shaped needle points (angle: 10°-12°, length: 1.0-1.2mm). The needle body is made of (b)(4) Product Specifications; the needle handle is made of (b)(4) Product, and the insertion tube is made of (b). The attachment of the needle body to the needle handle is done mechanically with inner hole of needle handle and the part of prominence and depression of the needle body for attachment, length 15mm). Single Pipe Handle Sterile Acupuncture Needles and Pipe Handle Sterile Acupuncture Needles have a pipe type needle handle. Spring Handle Sterile Acupuncture Needles have a spring shape needle handle.

[Drawing of Products]

(b)(4) Product Specifications



2. Body of Needle

Material: (b)(4) Product [redacted]
Length and Thickness: According needle's standard
Prominence and Depression: 15 mm



3. Handle of Needle

Material: (b)(4) Product [redacted]
Length: 20 mm
Outer diameter: ϕ 1.2 mm
Inner diameter: According to size of needle body

4. Tube for Needle

Material: ([redacted]
Length: According to
needle body
Outer diameter: 3.0 mm

(b)(4) Product Specifications [redacted]

5. Bulk Package for 10 Spring Needles and for 5 Pipe Needles

(b)(4) Product Specifications [redacted]

B. Pipe Type

(b)(4) Product Specifications [redacted]

1. Tip of Needle

(b)(4) Product Specifications [redacted]

2. Body of Needle

Material: (b)(4) Product [redacted]
Length and thickness: According to needle size
Prominence and Depression: 15mm



3. Handle of Needle

Material: (b)(4) Product Specification [redacted]
Length: 20 mm
Outer Diameter: ϕ 1.1 mm
Inner Diameter: According to size of needle body

(b)(4) Product Specifications [redacted]

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4. Insertion Tube of Needle

Material: (b)(4)
 Length: According to needle body
 Inner Diameter: ϕ 3.0 mm
 Outer Diameter: ϕ 2.0 mm

(b)(4) Product Specifications

5. Single Pipe Blister Package

Case: (b)(4) Product Specifications

(b)(4) Product Specifications

Sterilized Paper

(b)(4) Product Specifications

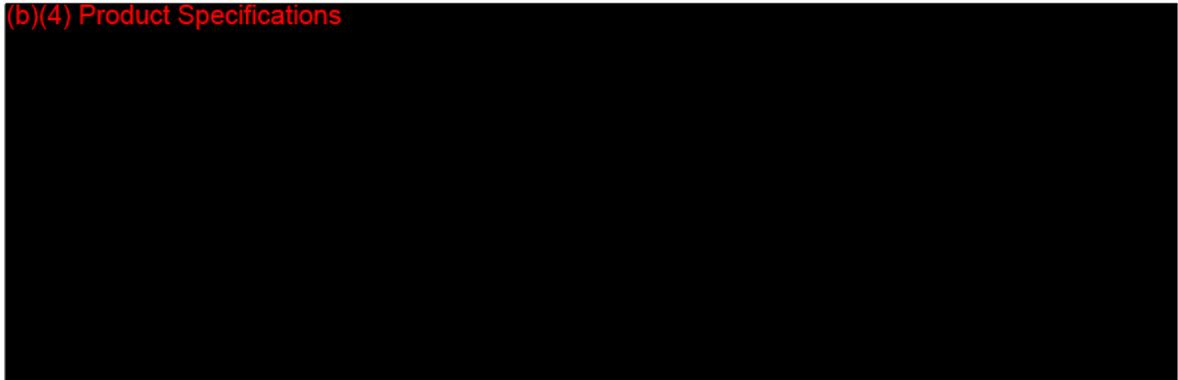
2-2-2 The Dimension of DBC, Dong Bang Acupuncture Needles

		Length of the needle in milimeter									
		7	15	30	40	50	60	75	90	120	160
Diameter of the needle in millimeter	0.16	o									
	0.18		o	o	o	o	o				
	0.20		o	o	o	o	o				
	0.22		o	o	o	o	o				
	0.25		o	o	o	o	o				
	0.26		o	o	o	o	o				
	0.28		o	o	o	o	o				
	0.30		o	o	o	o	o	o			
	0.35		o	o	o	o	o	o	o		
	0.40		o	o	o	o	o	o	o		
	0.45		o	o	o	o	o	o	o	o	
	0.50		o	o	o	o	o	o	o	o	
0.70							o	o	o	o	

3. MATERIAL IDENTIFICATION, BIOCOMPATIBILITY AND MECHANICAL TESTING

3-1 Material Identification

(b)(4) Product Specifications



3-2 Biocompatibility

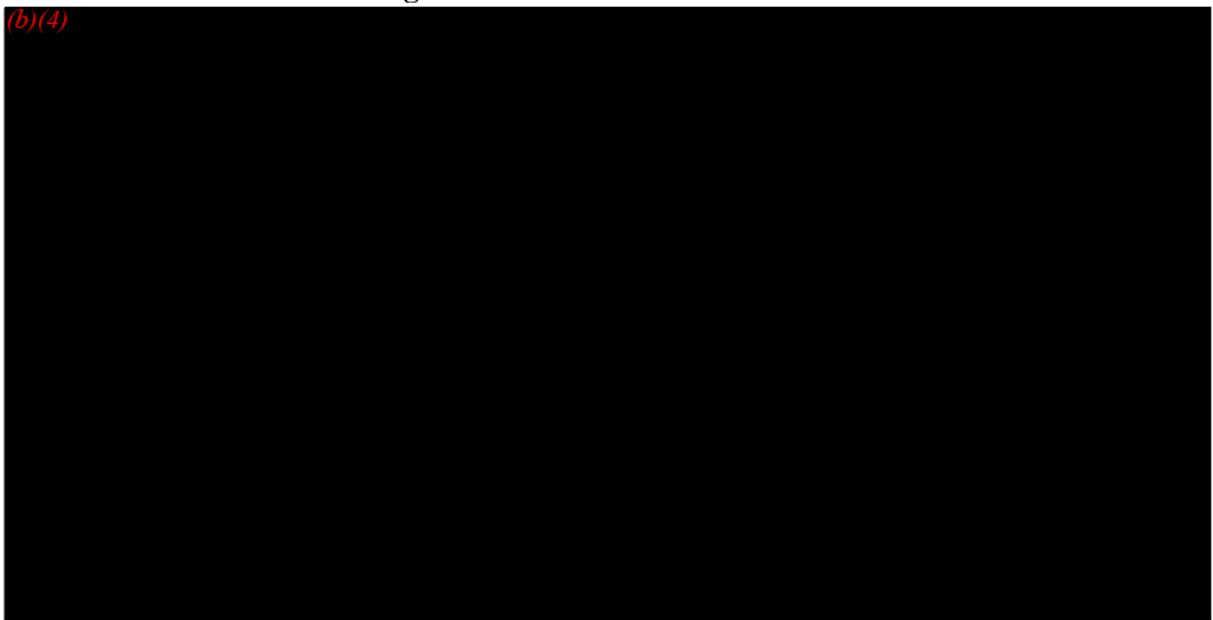
Stainless steel biocompatibility is established in use (b)(4) Product Specifications

All DBC, Dong Bong acupuncture needle bodies as discussed already are made of (b)(4) Product Specifications. The stainless steel wire in (b)(4) is identical to the **DBC Acupuncture Needle (K963300)**: "I, Ae-Hoe Kwon, president of MorningStar, Dong Bang Acupuncture U.S.A., Inc., certify that **DBC, Dong Bang Acupuncture Needle** is identical to the legally marketed **DBC Acupuncture Needle** (510(k) K963300)."

(Ae-Hoe Kwon) *Ae-Hoe Kwon* Date: *04/07/1999*

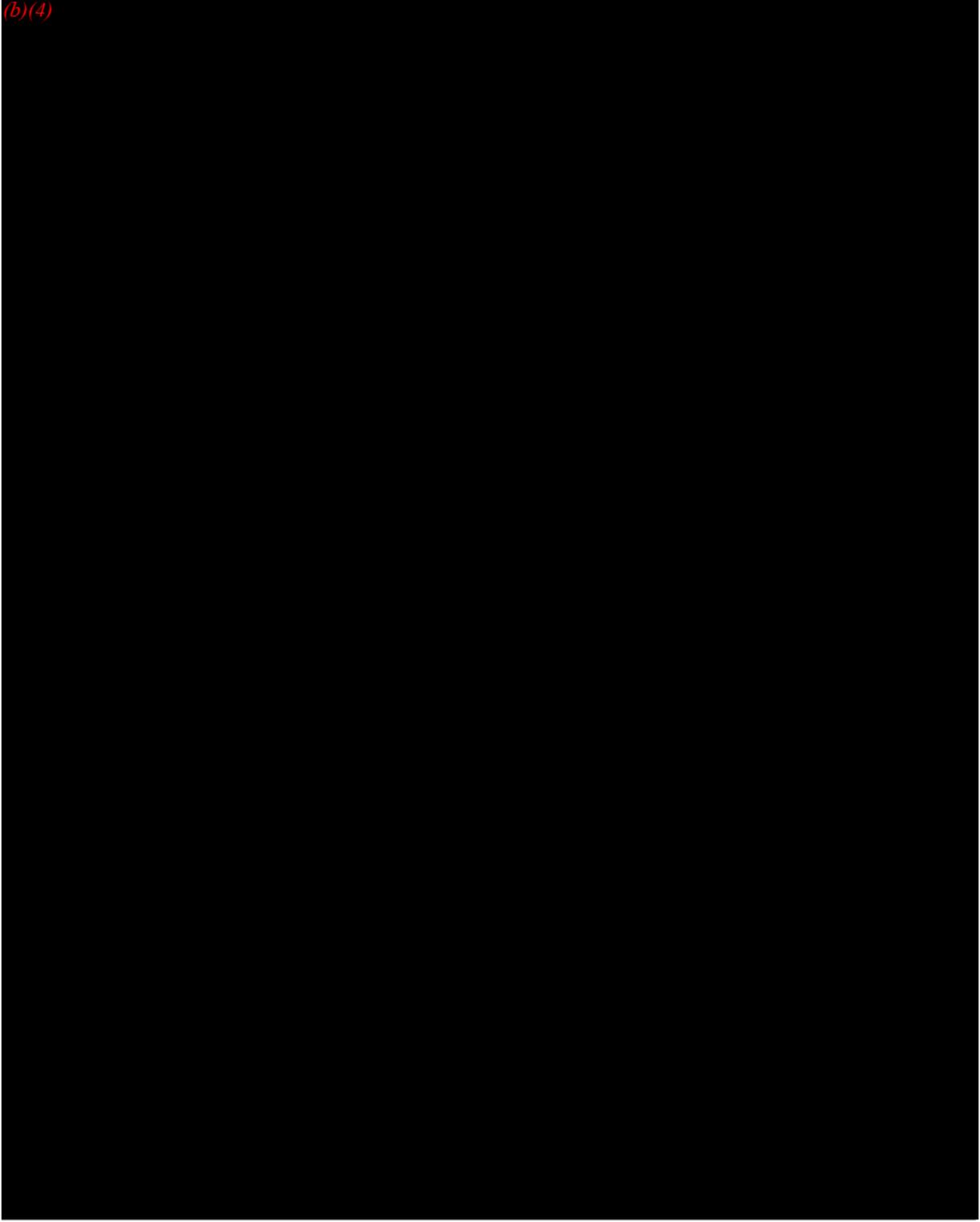
3-3 Mechanical Testing

(b)(4)



4. STERILIZATION INFORMATION

(b)(4)



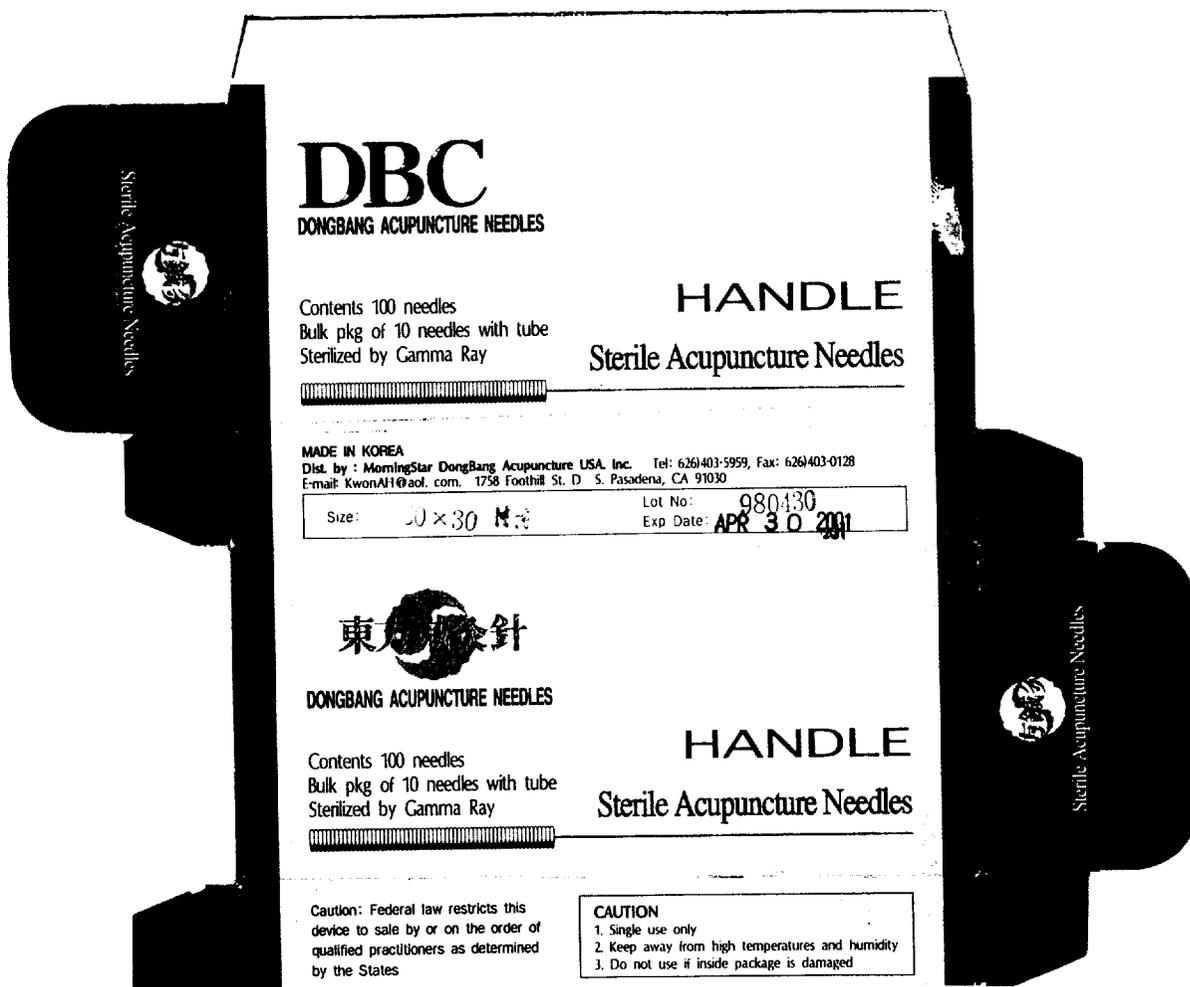
24

5. PROPOSED LABELING

5-1 The Various Types of Proposed Devices: Device and Package Labels

“DBC, Dong Bang Acupuncture Needles” have three types of needle names: (1) “Single Pipe Handle Sterile Acupuncture Needles,” (2) “Spring Handle Sterile Acupuncture Needles,” and (3) “Pipe Handle Sterile Acupuncture Needles” as follows:

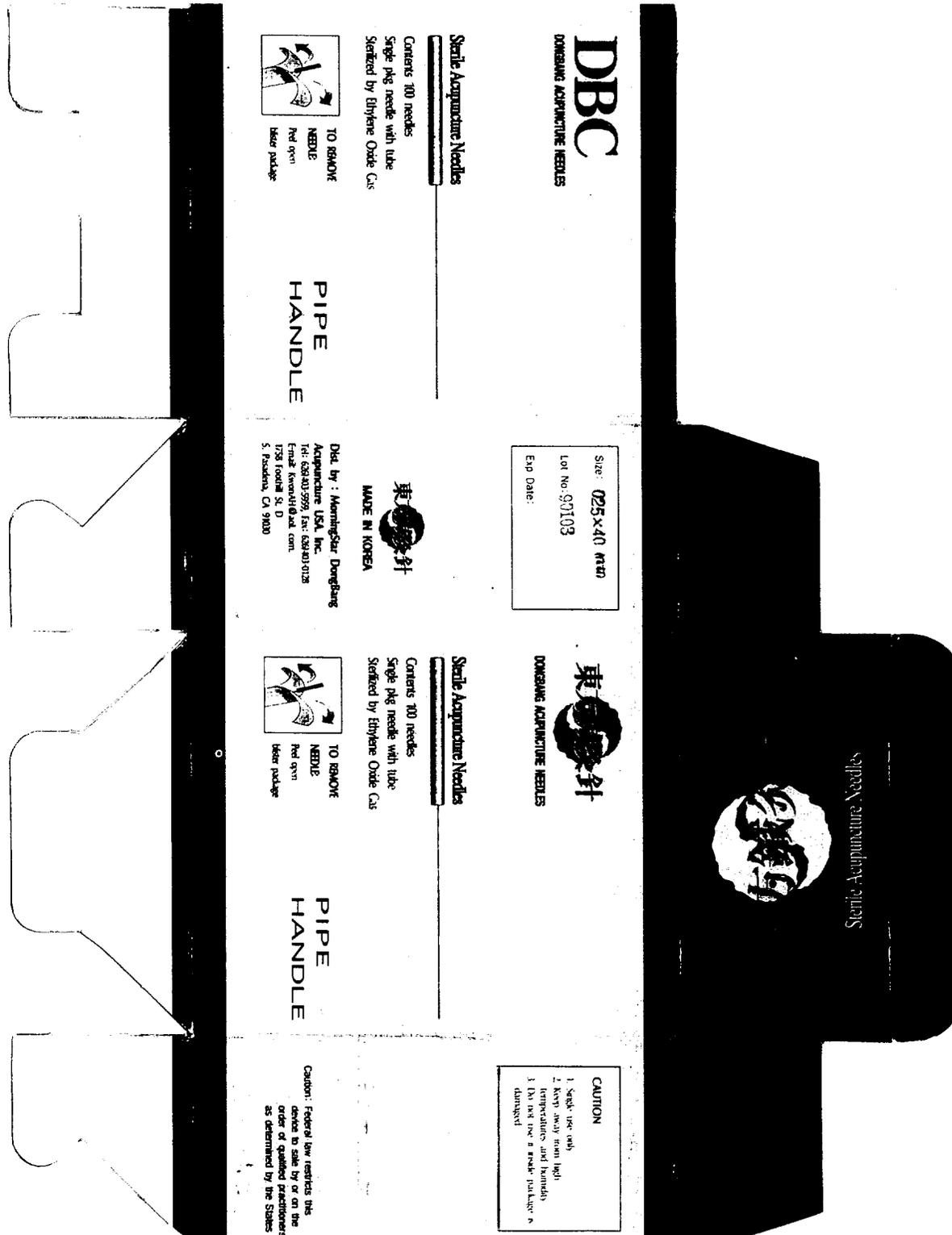
5-1-1 Spring Handle Sterile Acupuncture Needle Package



[100 sterilized and bulk spring handle needles in a box with a plastic insertion tube per 10 needles]

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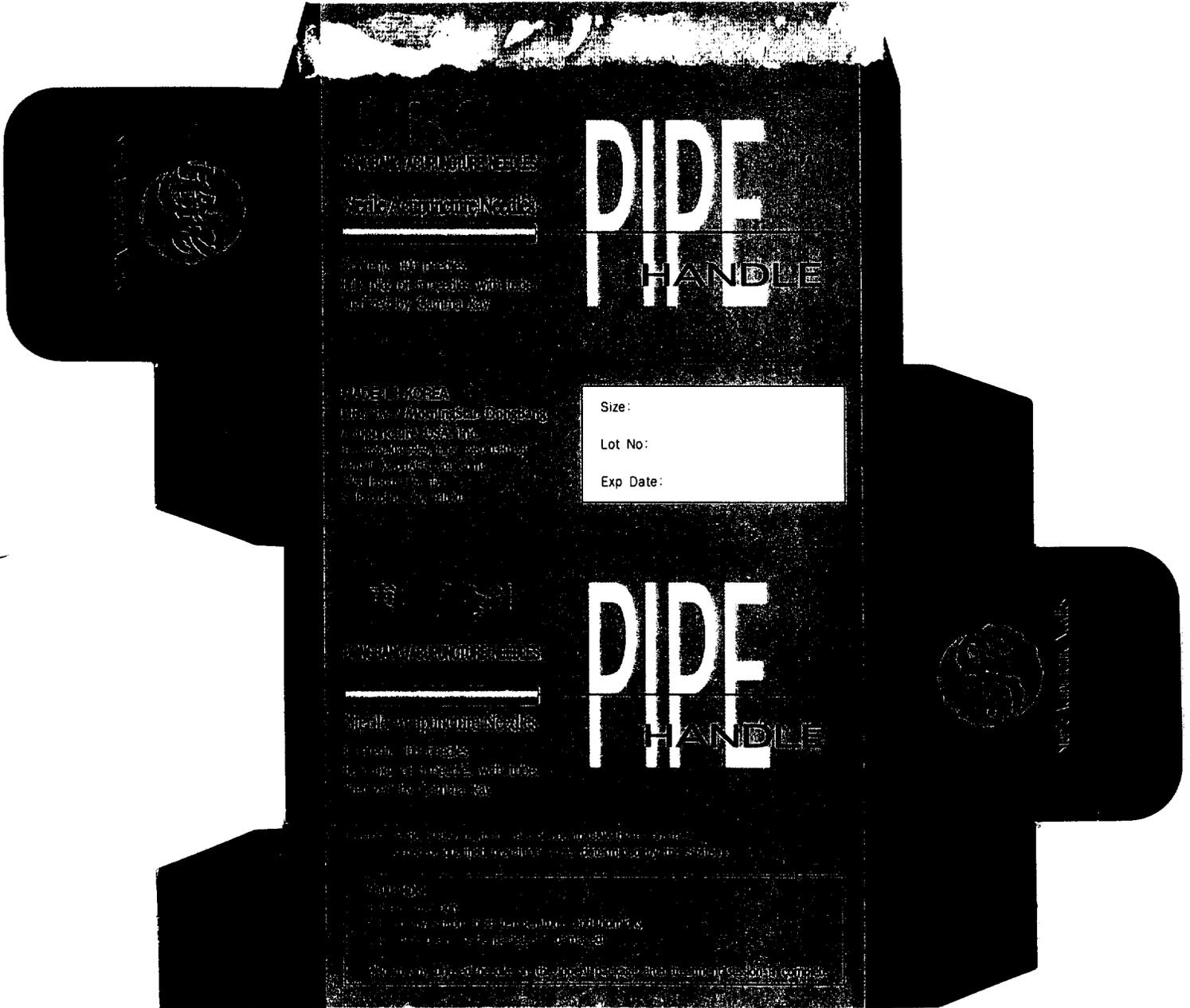
5-1-2 Single Pipe Handle Sterile Acupuncture Needle Package



[100 sterilized and sealed Pipe Blister needles in a box with a plastic insertion tube per needle]

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5-1-3 Pipe Handle Sterile Acupuncture Needle Package



[100 sterilized and bulked pipe handle needles in a box with a plastic insertion tube per 5 needles]

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5-2 Package Inserts: Sterile, Disposable Needle, Number and Quantity, and Insertion tube

“Single Pipe Handle Sterile Acupuncture Needles” are individually packaged with a pipe blister needle and a plastic insertion tube per each sterile sealed (EOG) blister package (PET + Sterile Paper). A small box is 100 needles. “Spring Handle Sterile Acupuncture Needles are packaged with 10 spring handle needles and a plastic insertion tube per each sterile (γ-ray) sealed bulk package (non-toxic PET + LLDPE). “Pipe Handle Sterile Acupuncture Needles” are packaged with 5 pipe handle needles and a plastic insertion tube per each sterile (γ-ray) sealed bulk package. These insertion tubes are made of (b) (4). A large box, with 1000 acupuncture needles, is packaged with 10 small boxes as described above (see the attached samples).

5-3 Size Indication

Sizes vary as mentioned above in 2-2-2. According to diameter and blade length, the DBC, Dong Bang acupuncture needles are indicated as “mm x mm” (i.e., 0.20mm x 40mm) by a stamp on the small box and the large box.

5-4 Prescription Statement

DBC, Dong Bang acupuncture needles are labeled as follows:

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution
1. Single use only.
 2. Keep away from high temperatures and humidity.
 3. Do not use if inside package is damaged.

Additionally, for bulk package (10 Spring or 5 Pipe handle needles):
Discard any unused needles in the (open) package after treatment session is complete.

As shown in the attached samples, the label and labeling of DBC, Dong Bang consists of package label, instructions for use, package inserts, and prompts: size, expiration date, sterility, types, guidance for distributor. The subject of this 510(k), the DBC, Dong Bang acupuncture needle has the same intended use as the DBC (K963300) and the same technological characteristics as the DBC.

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6. COMPARISON OF SUBSTANTIAL EQUIVALENCE

6-1 Table of Similarities and Differences

Similarity: o Difference: x

Division	DBC, Dong Bang	DBC	cf. (Dong Bang)
Intended use	o	o	general practice of acupuncture, single use only
Labeling	o	o	the same except trade name and distributor
Design of Device	o	o	fine leaf shaped tip, spring and pipe handle
Specifications	o	o	handle type: spring and pipe
Materials	o	o	18-8 surgical stainless steel wire (sus-304), brass & nickel chromed, PET+LLDPE
Biocompatibility	o	o	stainless steel
Chemical Safety	o	o	non-toxic
Mechanical Safety	o	o	safety tested for shape, bending, twisting, elasticity, and needle handle bond strength
Performance	o	o	qualified practitioner
Radiation Safety	o	o	<25ppm, 25kgy
Standards met	o	o	safety and effectiveness
Sterility	o	o	sterile (γ-ray or EOG for Dong Bang)
Thermal safety	o	o	pyrogen free
Trade name, distributor in labeling	x	x	a new 510 (k) needed for marketing

6-2 Analysis and Information about Safety and Effectiveness

6-2-1 Comparative Analysis between the Two Devices

Acupuncture needles of two trade names are manufactured by the same manufacture, Dong Bang Medical Co., LTD. For the purpose of marketing through a new trade name and distributor, the different specializations are indicated as follows:

	DBC, Dong Bang Acupuncture Needle	DBC Acupuncture Needle
Name	DBC, Dong Bang Acupuncture Needles	DBC
distributor	Morning Star, Dong Bang Acu. Inc.	Lhasa Medical, Inc.

The differences of trade name, guidance for distributor, color and design in package labeling do not affect the intended use or technical characteristics of the acupuncture needles. Instructions for use, package inserts, sterility, types, materials, and physical specializations are the same between the two devices.

6-2-2 Information about the Two Devices' Safety and Effectiveness

Dong Bang Medical Co., LTD's acupuncture needles of Korea have been imported and sold through commercial interstate distribution to the U.S.A. by Dong Bang USA, Inc. (510(k) number: K972659), Lhasa Medical, Inc. (510(k) number: K963300) since 1988. At this time, no accident or device failure claims have been reported as a result of using the DBC, Dong Bang acupuncture needles of Korea. Dong Bang Medical Co., LTD, DBC bear a "Q"(qualified) mark by which Korea government guarantees needle quality, safety and effectiveness. Dong Bang Medical Co., LTD has 4 technological patent rights by the Office of Patent Administration (OPA) of Korea (see p. 17, Internet Home Page, [http://www. DongBangC.co.kr](http://www.DongBangC.co.kr) of Dong Bang Acupuncture Needles Co.)

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. At this time, we are not aware of any serious or life-threatening accidents involving acupuncture needles. The proposed DBC, Dong Bang Acupuncture Needles as a new trade name for DBC acupuncture needles which are currently being marketed through interstate distribution, offer greater safety, since they are sterile (γ -ray and EOG), single use only, stainless and non-pyrogenic acupuncture needles, as suggested in the above description and sterilization of the device.

The subject of this 510(k) application, DBC, Dong Bang Acupuncture Needles, as a γ -ray or EOG sterile, single use only acupuncture needle, is not only safe, but also meets the physical specifications, biocompatibility, mechanical testing criterion for an acupuncture needle and is effective for the practice of acupuncture as discussed in the preceding chapters.

The proposed Dong Bang, DBC acupuncture needle is safe and effective, non-toxic, non-pyrogenic, painless, uniform, and smooth in insertion. The subject of this 510(k) application, the DBC, Dong Bang acupuncture needle is **identical** to the legally marketed DBC acupuncture needle (K963300).

7. ADVERTISEMENT FOR DONG BANG, DBC PRODUCTS

Dong Bang Medical Co., LTD has activated the commercial advertisements through catalogs, magazines, and Internet Home Page (<http://www.DongBangC.co.kr>).

7-1 Introduction to Dong Bang Medical Co., LTD

Company Information



Since November 24, 1987 with permission No.263 from government, our company has been established to produce disposable needles for medical treatment in traditional oriental hospitals.

With automatical production line, we invented the needle of high technique to reduce the pain of patients with special know-how, which is the first trial in Korea. And with ability to produce 8,000,000 pieces for domestic markets such as Kyunghee Medical Center, Wonkwang Univ. Hospital. And also we are planning to export some products, though it is small quantity, through local branches to foreign markets such as America.

Company History

- 1987. 06 Established Dong Bang Acupuncture, Inc.
- 1987. 11 Permission on manufacturing and treatment of medical instruments from Government (Ministry of Health No.263)
- 1991. 03 Established local branch in China
- 1997. 04 Q mark for guaranteeing the quality
- 1998. 04 Established local branch in the U.S.A.

Employees

19

Countries Exported to

America, England, Spain, EU

Regional Offices

MorningStar. DongBang Acupuncture U.S.A., Inc.
 (staff in charge: Ae-Hoe, Kwon)
 1429 Lyndon St.
 S. Pasadena, CA 91030
 E-mail; DBCacup@aol.com
 Tel ; 626-403-5959
 Fax ; 626-403-0128

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7-2 Technology, Certification and Products

Technology

Kinds	Items with permission	No.	The concerned authority	Date
Guarantee for quality	Stainless acupuncture needle	95-057	Korean Life Goods Test Research Institute	1997. 04. 23
Utility Design	Magnetic needle	071693	The Office of Patent Administration (OPA)	1995. 03. 30
Design Registration	Magnetic needle	071398	The Office of Patent Administration (OPA)	1995. 11. 10
Design Registration	Magnetic seal	071397	The Office of Patent Administration (OPA)	1995. 11. 10
Trademark Registration	D B C	297639	The Office of Patent Administration (OPA)	1994. 09. 03

Certifications



Products

- * Acupuncture needle:
 Disposable needle (named Blister: single)
 Spring and Pipe needle (sold by bulk),
 Long needle (Gold handle needle),
 Acupuncture needle for palm and many kinds
- * Moxa
 Indirect moxa, mini moxa, pipe-shaped moxa, moxa plate, etc.
- * Suction Instrument
- * Human body shape / the picture of blood fixed places

As shown above, Dong Bang Medical Co., LTD, DBC activates advertises through Internet Home Page, <http://www.DongBangC.co.kr>, Catalogs and "Giuep Nara," the magazine of "The Small and Medium Industry Promotion Corporation."

Handwritten mark resembling the number 32.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

March 16, 1999

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

MORNING STAR, DONG BANG ACUPUNCTURE 510(k) Number: K990328
1429 LYNDON ST. Product: DBC, DONG BANG
SOUTH PASADENA, CA 91030 ACUPUNCTURE
ATTN: AE-HOE KWON NEEDLES

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K990328/14^c

RECEIVED

MAR 8 3 02 PM '99

FDA/CDRH/OCE/DHC

510(K) NOTIFICATION

1. **Reason and Purpose for Submission:** This is a revised application with reference to a new 510(k) number: K990328 for Marketing through a new trade name, DBC, Dong Bang Acupuncture Needles.
 - This package replaces all old ones, except for appendixes.
 - Especially, please delete the phrase, "for electroacupuncture & moxibustion" (appendix 8-4 catalog), appendix 8-3, and appendix 8-5 including Korean pages. The patent for magnetic needles (appendix 8-5, p. 19-7) is not related to the proposed devices.
2. **A Legally Marketed Device:** DBC Acupuncture Needles, {510(k) No. K963300} submitted by Lhasa Medical, Inc. DBC Acupuncture Needle is identical to the subject of this application and is manufactured by Dong Bang Medical Co. LTD (DBC).
3. **Device Classification Name:** Needle, Acupuncture, Single Use
4. **Device Trade Name:** DBC, Dong Bang Acupuncture Needles
5. **Applicant:** Morning Star, Dong Bang Acupuncture U.S.A., Inc.
as a Regional Office of Dong Bang Medical Co., LTD
1429 Lyndon St.
S. Pasadena, CA 91030-3381
Tel: 626) 403-5959, Fax: 626) 403-0128
6. **Contact:** Ae-Hoe Kwon
7. **Product Code:** MQX
8. **Class:** II
9. **Medical Specialty (panel):** General Hospital (21 CFR Part 890)
10. **Manufacturer:** (b)(4)

(b)(4)

Date Submitted: January 28, 1999

(Ae-Hoe Kwon/Jan. 28, 1999)

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Dong Bang Acupuncture Needles Co., or DBC, is the same company. DBC is the brand name and abbreviation of Dong Bang Acupuncture Needles Co., and DBC has been patented to Keun-Sik Kim (president) by the Korean Patent Bureau since 1994. The company name has been changed to Dong Bang Medical Co., LTD. I will from here on out use Dong Bang Medical Co., LTD.

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MorningStar, Dong Bang 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:

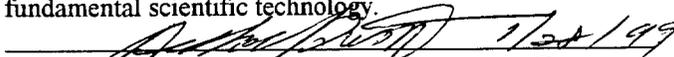
Acupuncture needles are defined as devices "intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States." Single use only acupuncture needles have been used for "the general practice of acupuncture" in the United States. The proposed 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 1/28/99

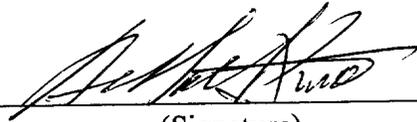
1429 Lyndon St.
S. Pasadena,
CA 91030-3381

T: 626) 403-5959
F: 403-0128
DBCacup@aol.com

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**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as “regional office staff in charge,” importer and the US designated agent of Dong Bang Medical Co., LTD (DBC), I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Ae-Hoe Kwon

(Typed Name)

01/28/1999

(Dated)

K

(Pre-market Notification [510(k)] Number)

510(K) NUMBER (IF KNOWN): K990328
DEVICE NAME: DBC, DONG BANG ACUPUNCTURE NEEDLES

INDICATIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution**
- 1. Single use only.**
 - 2. Keep away from high temperatures and humidity.**
 - 3. Do not use if inside package is damaged.**
- * {Discard any unused needles in the (open) package after treatment session is complete.}

* {} is for bulk package.

(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 _____
(Per 21 CFR 801.109) (Optional Format 1-2)

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1. GENERAL INFORMATION

1-1. The Name of Device

1-1-1 Trade Name: **DBC, Dong Bang Acupuncture Needles**

1-1-2 Common or Usual Name: **Acupuncture Needles**

1-1-3 Classification Name: **Needle, Acupuncture, Single Use**

1-2 The Class of Device: **Class II**

1-3 Medical Specialty (panel): **General Hospital (21 CFR Part 880)**

1-4 Product Code No: **MQX**

1-5 The Establishment Name and Registration Number

1-5-1 Manufacture Name: **Dong Bang Medical Co., LTD (DBC)**

* FDA Registration No: **8040810** (since 1988)

* Device Listing No: **B 008479**

* Address of Manufacturer:

(b)(4)

1-5-2 Applicant: **Morning Star, Dong Bang Acupuncture U.S.A., Inc.:**
Regional Office/the Sole US Agent designated by DBC
(see appendix 8-1)

* FDA Registration Form Operation and owner ID: **9034129**

* LA Regional Registration Form No: **2086502**

1-6 Purpose of Submission:

Since the current 510(k) K963300 (see appendix 8-3) belongs to the specific importer, the manufacturer or other importers are unable to use the current 510(k). For marketing a new trade name, DBC, Dong Bang Acupuncture Needles through a new importer, a new 510(k) number different from a legally marketed DBC is called for.

- This package is a revised application with reference to a **New 510(k) Number: K990328**. All old application documents must be replaced by this new one, except for appendixes. But please delete appendix 8-3 and 8-5.

1-7 A Legally Marketed Predicate Device: **DBC Acupuncture Needles, 510(k) Number. K963300.**

This 510(k) number was submitted by Lhasa Medical, Inc. and the acupuncture needles are manufactured by Dong Bang Medical Co., LTD (DBC). The subject of this application is identical with the DBC acupuncture needles as a predicate device for substantial equivalence (See appendix 8-7, copies of the DBC and the DBC, Dong Bang Acupuncture Needles' labeling).

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2. DESCRIPTION OF THE PROPOSED DEVICE

2-1 Statement of 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." Acupuncture needles have been used for "the general practice of acupuncture" in the United States. The DBC, Dong Bang acupuncture needles have only the intended use and indication for use in labeling for the "general practice of acupuncture," without any other specific use or treatment.

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

Caution 1. Single use only.

2. Keep away from high temperatures and humidity.

3. Do not use if inside package is damaged.

(for bulk) Discard any unused needles in the (open) package after treatment session is complete.

2-2 Device Specifications

2-2-1 Physical Specifications

DBC, Dong Bang acupuncture needles have no visible defects in acupuncture needle body finishing under the magnification of 100 times. Their tips are (b)(4) Product Specifications. The needle body is made of (b)(4) Product Specifications, the needle handle is made (b)(4) and the insertion tube is made of (b)(4). The attachment of the needle body to the needle handle is done mechanically with inner hole of needle handle and the part of prominence and depression of the needle body for attachment, length 15mm). Single Pipe Handle Sterile Acupuncture Needles and Pipe Handle Sterile Acupuncture Needles have a pipe type needle handle. Spring Handle Sterile Acupuncture Needles have a spring shape needle handle.

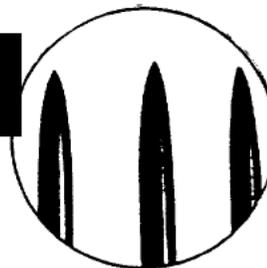
[Drawing of Products]

A. Spring Type

(b)(4) Product Specifications

1. Tip of Needle

(b)(4) Product Specifications



Pine Leaf Shaped Needle Point

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2. Body of Needle

Material: (b)(4) Product
Length and Thickness: According needle's standard
Prominence and Depression: (b)(4)

(b)(4) Product Specifications

3. Handle of Needle

Material: (b)(4) Product
Length: 20 mm
Outer diameter: ϕ 1.2 mm
Inner diameter: According to size of needle body

(b)(4) Product Specifications

4. Tube for Needle

Material: (b)(4)
Length: According to needle body
Outer diameter: 3.0 mm
Inner diameter: 2.0 mm

(b)(4) Product Specifications

5. Bulk Package for 10 Spring Needles and for 5 Pipe Needles

(b)(4) Product Specifications

B. Pipe Type

(b)(4) Product Specifications

1. Tip of Needle

(b)(4) Product Specifications

2. Body of Needle

Material: (b)(4) Product Specifications
Length and thickness: According to needle size
Prominence and Depression: (b)(4)

(b)(4) Product Specifications

3. Handle of Needle

Material: (b)(4) Product Specifications
Length: 20 mm
Outer Diameter: ϕ 1.1 mm
Inner Diameter: According to size of needle body

(b)(4) Product Specifications

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- 4. Insertion Tube of Needle
 Material: (b)(4)
 Length: According to needle body
 Inner Diameter: ϕ 3.0 mm
 Outer Diameter: ϕ 2.0 mm

(b)(4) Product Specifications

- 5. Single Pipe Blister Package
 Case:

(b)(4) Product Specifications

Sterilized Paper

(b)(4) Product Specifications

2-2-2 All Sizes of DBC, Dong Bang Acupuncture Needles

o: The Proposed Acupuncture Needle Sizes

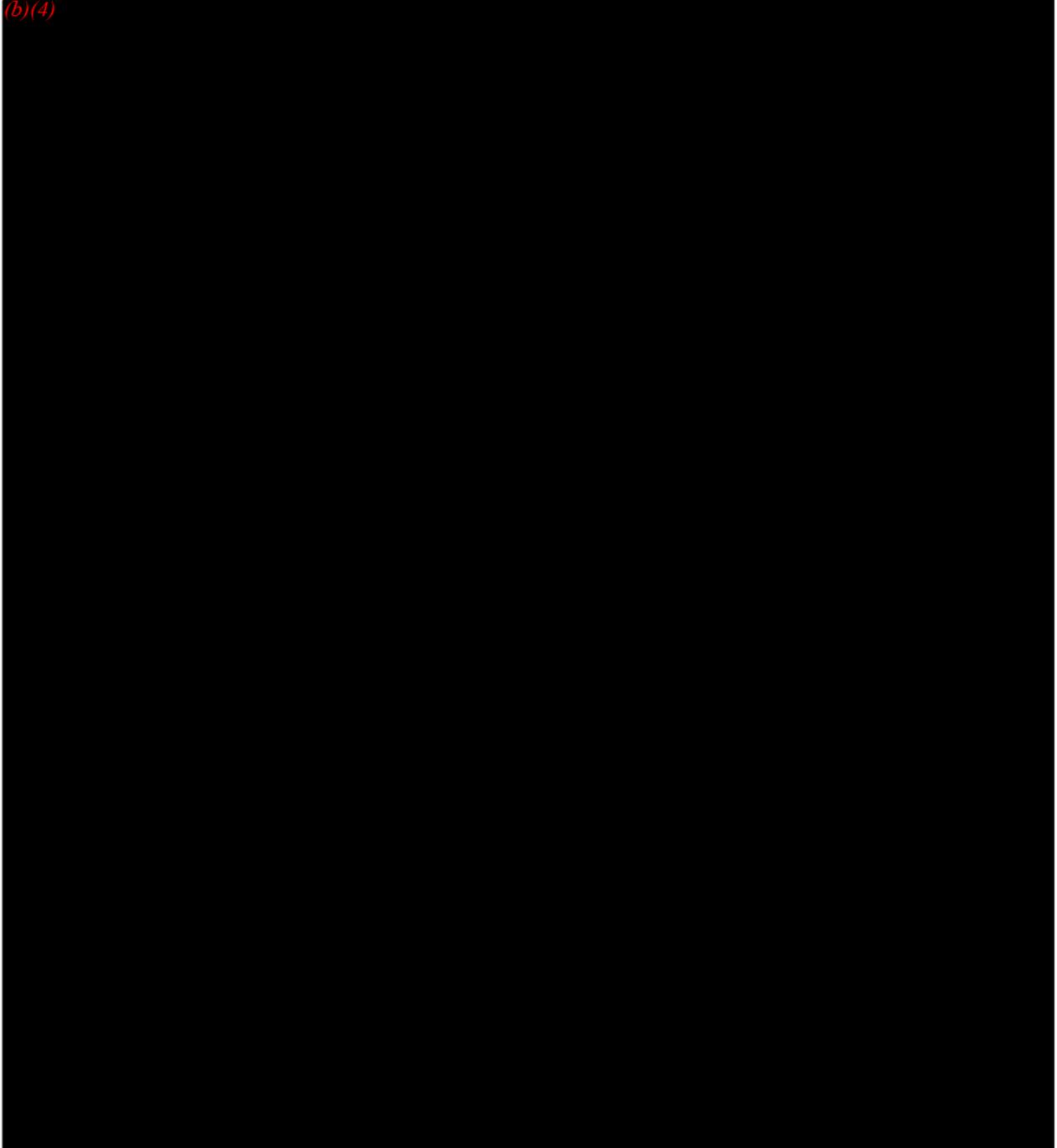
Blade Diameter	Blade Length									
	7 mm	15 mm	30 mm	40 mm	50 mm	60 mm	75 mm	90 mm	120 mm	160 mm
0.16	o									
0.18		o	o	o	o	o				
0.20		o	o	o	o	o				
0.22		o	o	o	o	o				
0.25		o	o	o	o	o				
0.26		o	o	o	o	o				
0.28		o	o	o	o	o				
0.30		o	o	o	o	o	o			
0.35		o	o	o	o	o	o	o		
0.40		o	o	o	o	o	o	o		
0.45		o	o	o	o	o	o	o	o	
0.50		o	o	o	o	o	o	o	o	
0.70						o	o	o	o	o

All sizes are indicated as “(Blade Diameter) mm x (Blade Length) mm.”

Dr

**3. MATERIAL IDENTIFICATION, BIOCOMPATIBILITY
AND MECHANICAL TESTING**

(b)(4)



43

4. STERILIZATION INFORMATION

(b)(4)



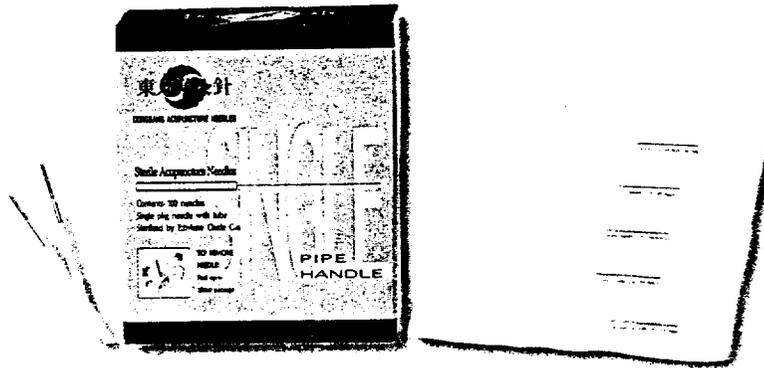
AA

5. PROPOSED LABELING

5-1 The Various Types of Proposed Devices: Device and Package Labels

“DBC, Dong Bang Acupuncture Needles” have three types of needle names: (1) “Single Pipe Handle Sterile Acupuncture Needles,” (2) “Spring Handle Sterile Acupuncture Needles,” and (3) “Pipe Handle Sterile Acupuncture Needles” as follows:

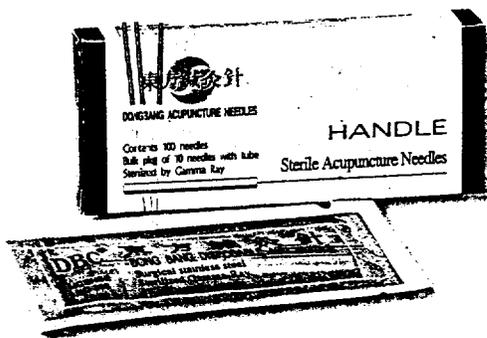
[Single Pipe Handle Sterile Acupuncture Needles]



● DBC1-1

{Pipe Blister Needle: Box of 100 Needles: 1 Needle with a Plastic Insertion Tube per Each Sterile(EOG) Sealed Blister Package}

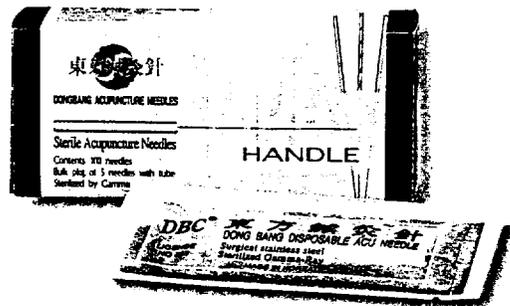
[Spring Handle Sterile Acupuncture Needles]



● DBC1-2

{Spring Bulk Needle: Box of 100 Needles: 10 Needles with a Plastic Insertion Tube per Each Sterile (γ-ray) Sealed Bulk Package}

[Pipe Handle Sterile Acupuncture Needles]



● DBC1-3

{Pipe Bulk Needle: Box of 100 Needles: 5 Needles with a Plastic Insertion Tube per Each Sterile (γ-ray) Sealed Bulk Package}

* Please see samples suggested for labeling (appendix 8-6, #).

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5-2 Package Inserts: Sterile, Disposable Needle, Number and Quantity, and Insertion tube

“Single Pipe Handle Sterile Acupuncture Needles” are individually packaged with a pipe blister needle and a plastic insertion tube per each sterile sealed (EOG) blister package (PET + Sterile Paper). A small box is 100 needles. “Spring Handle Sterile Acupuncture Needles are packaged with 10 spring handle needles and a plastic insertion tube per each sterile (γ -ray) sealed bulk package (non-toxic PET + LLDPE). “Pipe Handle Sterile Acupuncture Needles” are packaged with 5 pipe handle needles and a plastic insertion tube per each sterile (γ -ray) sealed bulk package. These insertion tubes are made of PP. A large box, with 1000 acupuncture needles, is packaged with 10 small boxes as described above (see the above picture and the samples of appendix 8-6, #).

5-3 Size Indication

Sizes vary as mentioned above in 2-2-2. According to blade diameter and blade length, the DBC, Dong Bang acupuncture needles are indicated as “mm x mm” (i.e., 0.20mm x 40mm) by a stamp on the small box and the large box.

5-4 Prescription Statement

DBC, Dong Bang acupuncture needles are labeled as follows:

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution
1. Single use only.
 2. Keep away from high temperatures and humidity.
 3. Do not use if inside package is damaged.

Additionally, for bulk package (10 Spring or 5 Pipe handle needles):

Discard any unused needles in the (open) package after treatment session is complete.

As shown in the attached samples, the label and labeling of DBC, Dong Bang consists of package label, instructions for use, package inserts, and prompts: size, expiration date, sterility, types, guidance for distributor. The subject of this 510(k), the DBC, Dong Bang acupuncture needle has the same intended use as the DBC (K963300) and the same technological characteristics as the DBC.

6. COMPARISON OF SUBSTANTIAL EQUIVALENCE

6-1 Table of Similarities and Differences

Similarity: o Difference: x

Division	DBC, Dong Bang	DBC	cf. (Dong Bang)
Intended use	o	o	general practice of acupuncture, single use only
Labeling	o	o	the same except trade name and distributor
Design of Device	o	o	fine leaf shaped tip, spring and pipe handle
Specifications	o	o	handle type: spring and pipe
Materials	o	o	18-8 surgical stainless steel wire (sus-304), brass & nickel chromed, PET+LLDPE
Biocompatibility	o	o	stainless steel
Chemical Safety	o	o	non-toxic
Mechanical Safety	o	o	safety tested for shape, bending, twisting, elasticity, and needle handle bond strength
Performance	o	o	qualified practitioner
Radiation Safety	o	o	<25ppm, >25kgy
Standards met	o	o	safety and effectiveness
Sterility	o	o	sterile (γ-ray or EOG for Dong Bang)
Thermal safety	o	o	pyrogen free
Trade name, distributor in labeling	x	x	a new 510 (k) needed for marketing

6-2 Analysis and Information about Safety and Effectiveness

6-2-1 Comparative Analysis between the Two Devices

Acupuncture needles of two trade names are manufactured by the same manufacture, Dong Bang Medical Co., LTD. For the purpose of marketing through a new trade name and distributor, the different specializations are indicated as follows:

	DBC, Dong Bang Acupuncture Needle	DBC Acupuncture Needle
Name	DBC, Dong Bang Acupuncture Needles	DBC
distributor	Morning Star, Dong Bang Acu. Inc.	Lhasa Medical, Inc.

The differences of trade name, guidance for distributor, color and design in package labeling do not affect the intended use or technical characteristics of the acupuncture needles. Instructions for use, package inserts, sterility, types, materials, and physical specializations are the same between the two devices.

6-2-2 Information about the Two Devices' Safety and Effectiveness

Dong Bang Medical Co., LTD's acupuncture needles of Korea have been imported and sold through commercial interstate distribution to the U.S.A. by Dong Bang USA, Inc. (510(k) number: K972659), Lhasa Medical, Inc. (510(k) number: K963300) since 1988. At this time, no accident or device failure claims have been reported as a result of using the DBC, Dong Bang acupuncture needles of Korea. Dong Bang Medical Co., LTD, DBC bear a "Q"(qualified) mark by which Korea government guarantees needle quality, safety and effectiveness. Dong Bang Medical Co., LTD has 4 technological patent rights by the Office of Patent Administration (OPA) of Korea (see p. 17, Internet Home Page, <http://www.DongBangC.co.kr> of Dong Bang Acupuncture Needles Co.)

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. At this time, we are not aware of any serious or life-threatening accidents involving acupuncture needles. The proposed DBC, Dong Bang Acupuncture Needles as a new trade name for DBC acupuncture needles which are currently being marketed through interstate distribution, offer greater safety, since they are sterile (γ -ray and EOG), single use only, stainless and non-pyrogenic acupuncture needles, as suggested in the above description and sterilization of the device.

The subject of this 510(k) application, DBC, Dong Bang Acupuncture Needles, as a γ -ray or EOG sterile, single use only acupuncture needle, is not only safe, but also meets the physical specifications, biocompatibility, mechanical testing criterion for an acupuncture needle and is effective for the practice of acupuncture as discussed in the preceding chapters.

The proposed Dong Bang, DBC acupuncture needle is safe and effective, non-toxic, non-pyrogenic, painless, uniform, and smooth in insertion. The subject of this 510(k) application, the DBC, Dong Bang acupuncture needle is **identical** to the legally marketed DBC acupuncture needle (K963300).

7. ADVERTISEMENT FOR DONG BANG, DBC PRODUCTS

Dong Bang Medical Co., LTD has activated the commercial advertisements through catalogs, magazines, and Internet Home Page (<http://www.DongBangC.co.kr>).

7-1 Introduction to Dong Bang Medical Co., LTD

Company Information



Since November 24, 1987 with permission No.263 from government, our company has been established to produce disposable needles for medical treatment in traditional oriental hospitals.

With automatical production line, we invented the needle of high technique to reduce the pain of patients with special know-how, which is the first trial in Korea. And with ability to produce 8,000,000 pieces for domestic markets such as Kyunghee Medical Center, Wonkwang Univ. Hospital. And also we are planning to export some products, though it is small quantity, through local branches to foreign markets such as America.

Company History

- 1987. 06 Established Dong Bang Acupuncture, Inc.
- 1987. 11 Permission on manufacturing and treatment of medical instruments from Government (Ministry of Health No.263)
- 1991. 03 Established local branch in China
- 1997. 04 Q mark for guaranteeing the quality
- 1998. 04 Established local branch in the U.S.A.

Employees

19

Countries Exported To

America, England, Spain, EU

Regional Offices

MorningStar. DongBang Acupuncture U.S.A., Inc.
 (staff in charge: Ae-Hoe, Kwon)
 1429 Lyndon St.
 S. Pasadena, CA 91030
 E-mail; DBCacup@aol.com
 Tel ; 626-403-5959
 Fax ; 626-403-0128

AA

7-2 Technology, Certification and Products

Technology

Kinds	Items with permission	No.	The concerned authority	Date
Guarantee for quality	Stainless acupuncture needle	95-057	Korean Life Goods Test Research Institute	1997. 04. 23
Utility Design	Stainless needle	071693	The Office of Patent Administration (OPA)	1995. 03. 30
Design Registration	Stainless needle	071398	The Office of Patent Administration (OPA)	1995. 11. 10
Design Registration	Stainless needle	071397	The Office of Patent Administration (OPA)	1995. 11. 10
Trademark Registration	D B C	297639	The Office of Patent Administration (OPA)	1994. 09. 03

Certifications



Products

- * Acupuncture needle:
 Disposable needle (named Blister: single)
 Spring and Pipe needle (sold by bulk),
 Long needle (Gold handle needle),
 Acupuncture needle for palm and many kinds
- * Moxa
 Indirect moxa, mini moxa, pipe-shaped moxa, moxa plate, etc.
- * Suction Instrument
- * Human body shape / the picture of blood fixed places

As shown above, Dong Bang Medical Co., LTD, DBC activates advertises through Internet Home Page, <http://www.DongBangC.co.kr>, Catalogs and "Giuep Nara," the magazine of "The Small and Medium Industry Promotion Corporation."

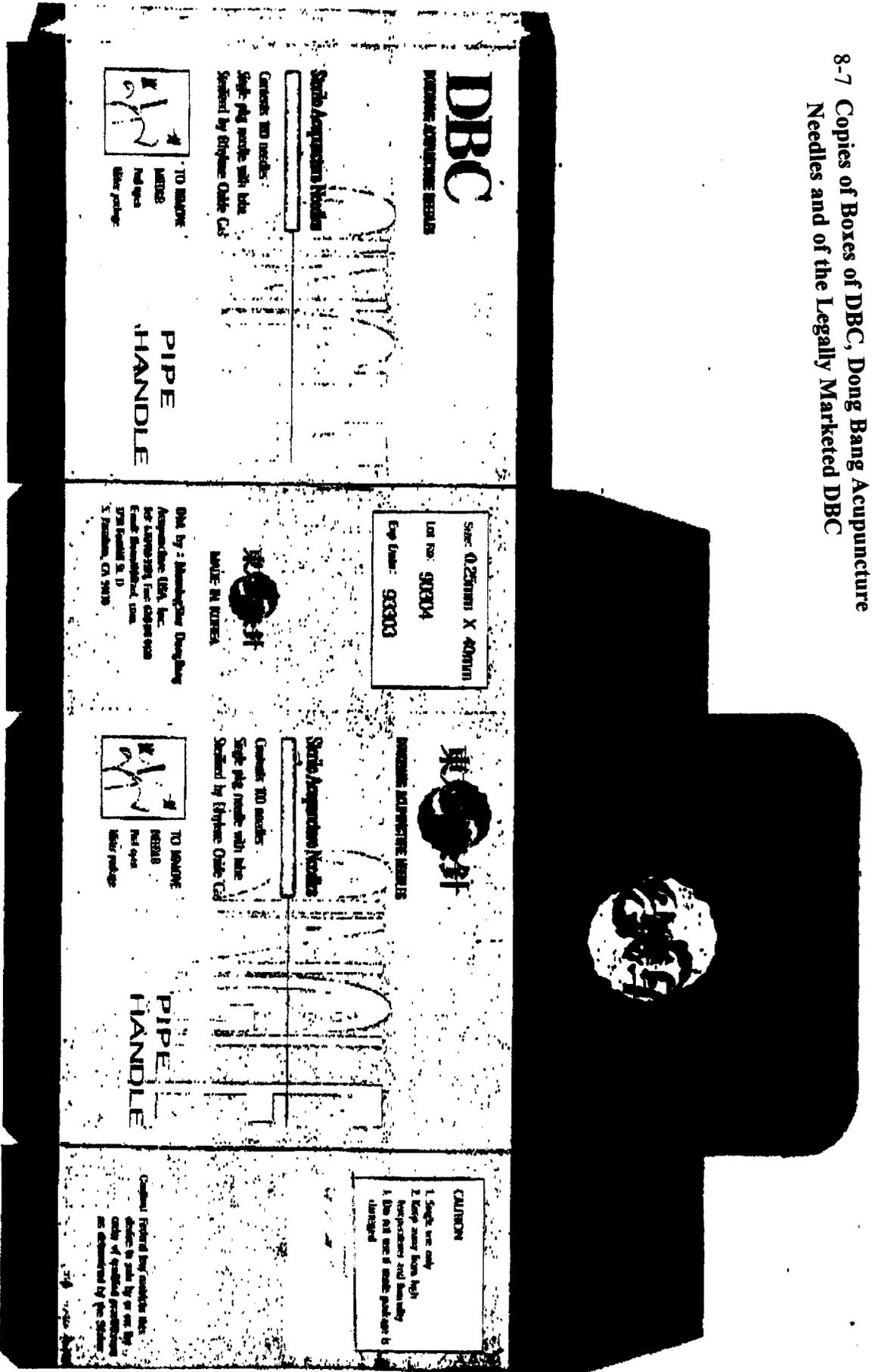
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8. APPENDIXES

8-1 The Letter of Authorization	19
8-2 510 (k) No (K963300) Submitted by Lhasa Medical, Inc.	20
8-4 Dong Bang Medical Co., LTD's Catalog	21
8-6 DBC, Dong Bang Acupuncture Needle Big Boxes (1000/ea) and Samples	#
8-7 Copies of Boxes of DBC and DBC, Dong Bang Acupuncture Needles	24

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8-7 Copies of Boxes of DBC, Dong Bang Acupuncture
Needles and of the Legally Marketed DBC



24-1

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DBC

DYNAMIC ACUPUNCTURE NEEDLES

Contains 100 needles
Bulk pkg of 10 needles with tube
Sterilized by Gamma Ray



HANDLE
Sterile Acupuncture Needles

MADE IN CHINA
Dist. by: Mandator Dynamic Acupuncture, Ltd. Inc. 145 Argonaut Blvd. San Dimas, CA 91773
Email: mandator@mandator.com IPM Facility No. D. S. Pasadena, CA 91104

Lot No: 903004
Exp Date: 03/30/03
Siz: 0.20mm X 30mm



DYNAMIC ACUPUNCTURE NEEDLES

Contains 100 needles
Bulk pkg of 10 needles with tube
Sterilized by Gamma Ray



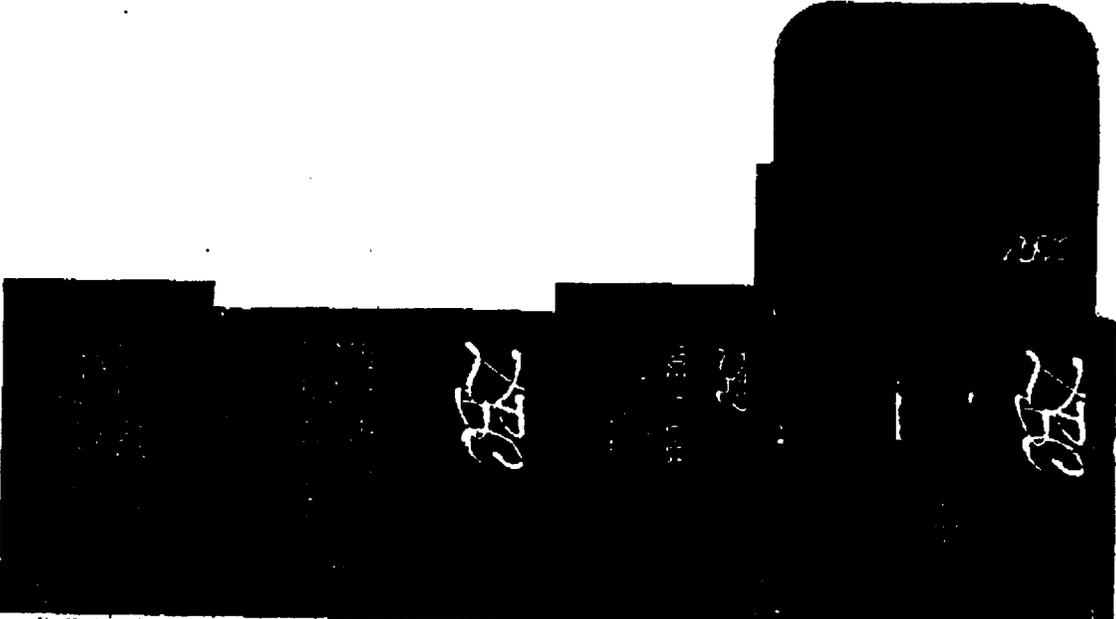
HANDLE
Sterile Acupuncture Needles

Caution: Federal law prohibits the
distribution to sale by or on the order of
any individual practitioner by individuals
other than the state

- CAUTION!**
1. Single use only
 2. Keep away from high temperatures and humidity
 3. Do not use if needle package is damaged

24-2

3



PHANDLE
Sterile Acupuncture Needles

Size 0.20mm X 30mm
Lot No. 90004

PHANDLE
Sterile Acupuncture Needles



- CAUTION**
1. Single use only
 2. Keep away from high temperatures and humidity
 3. Do not use if inside package is damaged
- Discard any unused needles in the (pink) package after treatment session is complete.

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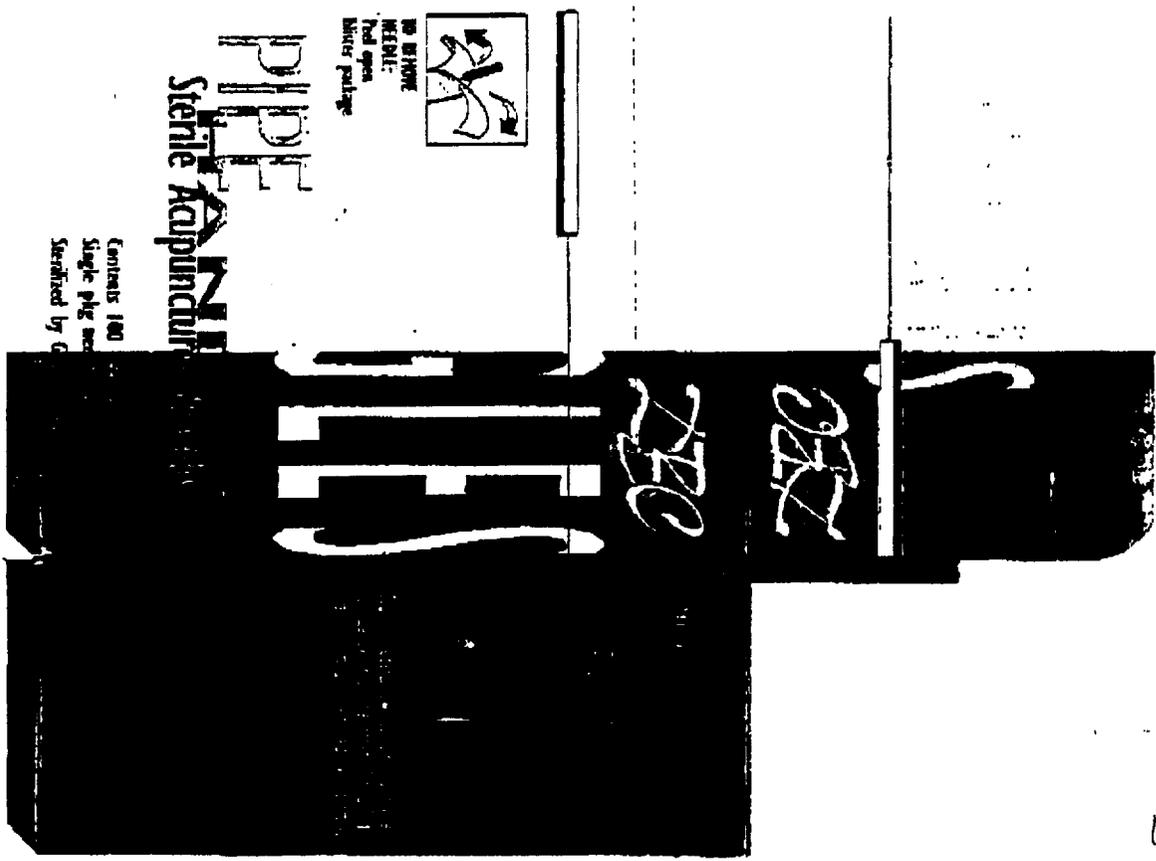
ANIP
Acupuncture Needles
Features: 100 needles
Single plug needle with auto
sterilized by Gamma Ray

MADE IN KOREA
Dae Yeon Medical, Inc., Seoul, KR
1-800-322-8735

Lot No. 903004

Size: 0.30mm X 50mm

24-4



ZFC
NO MIXING
NEEDLE:
Not open
Single package

ANIP
Sterile Acupuncture
PIPPE
Contents: 100
Single plug needles
Sterilized by Gamma Ray

55

K990328/A²SI

Ae-Hoe Kwon
MorningStar, DongBang 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

March. 4, 1999

FDA/CDRH
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED
MAR 03 02 PM '99
FDA/CDRH/OCE/DMC

Ref.: 510(k) Number: K990328
Device Name: DBC, Dong Bang Acupuncture Needles

This is a revised application with reference to a new 510(k) number: K990328 for Marketing through a new trade name, DBC, Dong Bang Acupuncture Needles.

- This package replaces all old ones, except for appendixes.
- Especially, please delete the phrase, "for electroacupuncture & moxibustion" (appendix 8-4 catalog), appendix 8-3, and appendix 8-5 including Korean pages. And, appendix 8-7, "Copies of Boxes of DBC, Dong Bang Acupuncture Needles and of the Legally Marketed DBC Acupuncture Needles, is added.

Thank you very much.

Sincerely yours,


Ae-Hoe Kwon 3/94/1999

SK46

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FDA/CDRH/OCE/DIC

JAN 28 3 02 PM '99

510(K) NOTIFICATION

1. **Reason and Purpose for Submission:** This is a revised application with reference to a new 510(k) number: **K990328** for Marketing through a new trade name, DBC, Dong Bang Acupuncture Needles.

- This package replaces all old ones, except for appendixes.
- Especially, please delete the phrase, "for electroacupuncture & moxibustion" (appendix 8-4 catalog), appendix 8-3, and appendix 8-5 including Korean pages. The patent for magnetic needles (appendix 8-5, p. 19-7) is not related to the proposed devices.

2. **A Legally Marketed Device:** DBC Acupuncture Needles, {**510(k) No. K963300**} submitted by Lhasa Medical, Inc. DBC Acupuncture Needle is identical to the subject of this application and is manufactured by Dong Bang Medical Co. LTD (DBC).

3. **Device Classification Name:** Needle, Acupuncture, Single Use

4. **Device Trade Name:** DBC, Dong Bang Acupuncture Needles

5. **Applicant:** Morning Star, Dong Bang Acupuncture U.S.A., Inc.
as a Regional Office of Dong Bang Medical Co., LTD
1429 Lyndon St.
S. Pasadena, CA 91030-3381
Tel: 626) 403-5959, Fax: 626) 403-0128

6. **Contact:** Ae-Hoe Kwon

7. **Product Code:** MQX

8. **Class:** II

9. **Medical Specialty (panel):** General Hospital (21 CFR Part 880)

10. **Manufacturer:** [REDACTED] (b)(4)

Date Submitted: January 28, 1999


(Ae-Hoe Kwon/Jan. 28, 1999)

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8-6 DBC, Dong Bang Acupuncture Needle Big Boxes (1000 pieces) and Samples	#

Dong Bang Acupuncture Needles Co., or DBC, is the same company. DBC is the brand name and abbreviation of Dong Bang Acupuncture Needles Co., and DBC has been patented to Keun-Sik Kim (president) by the Korean Patent Bureau since 1994. The company name has been changed to Dong Bang Medical Co., LTD. I will from here on out use Dong Bang Medical Co., LTD.

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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:

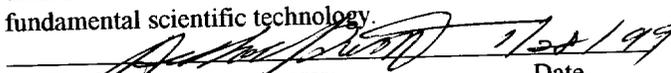
Acupuncture needles are defined as devices "intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States." Single use only acupuncture needles have been used for "the general practice of acupuncture" in the United States. The proposed 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.

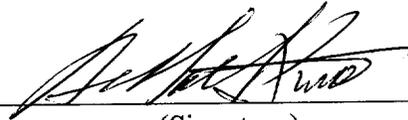

Ae-Hoe Kwon, contact person Date 1/28/99

1429 Lyndon St.
S. Pasadena,
CA 91030-3381

T: 626) 403-5959
F: 403-0128
DBCacup@aol.com

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as "regional office staff in charge," importer and the US designated agent of Dong Bang Medical Co., LTD (DBC), I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Ae-Hoe Kwon

(Typed Name)

01/28/1999

(Dated)

K

(Pre-market Notification [510(k)] Number)

60

510(K) NUMBER (IF KNOWN): K990328

DEVICE NAME: DBC, DONG BANG ACUPUNCTURE NEEDLES

INDICATIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution**
- 1. Single use only.**
 - 2. Keep away from high temperatures and humidity.**
 - 3. Do not use if inside package is damaged.**
- * {Discard any unused needles in the (open) package after treatment session is complete.}**

*** {} is for bulk package.**

(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 _____
(Per 21 CFR 801.109) (Optional Format 1-2)

b1

1. GENERAL INFORMATION

1-1. The Name of Device

- 1-1-1 Trade Name: **DBC, Dong Bang Acupuncture Needles**
- 1-1-2 Common or Usual Name: **Acupuncture Needles**
- 1-1-3 Classification Name: **Needle, Acupuncture, Single Use**

1-2 The Class of Device: **Class II**

1-3 Medical Specialty (panel): **General Hospital** (21 CFR Part 880)

1-4 Product Code No: **MQX**

1-5 The Establishment Name and Registration Number

1-5-1 Manufacture Name: **Dong Bang Medical Co., LTD (DBC)**

- * FDA Registration No: **8040810** (since 1988)
- * Device Listing No: **B 008479**
- * Address of Manufacturer:

(b)(4)



1-5-2 Applicant: **Morning Star, Dong Bang Acupuncture U.S.A., Inc.:** Regional Office/the Sole US Agent designated by DBC (see appendix 8-1)

- * FDA Registration Form Operation and owner ID: **9034129**
- * LA Regional Registration Form No: **2086502**

1-6 Purpose of Submission:

Since the current 510(k) K963300 (see appendix 8-3) belongs to the specific importer, the manufacturer or other importers are unable to use the current 510(k). For marketing a new trade name, DBC, Dong Bang Acupuncture Needles through a new importer, a new 510(k) number different from a legally marketed DBC is called for.

- This package is a revised application with reference to a **New 510(k) Number: K990328**. All old application documents must be replaced by this new one, except for appendixes. But please delete appendix 8-3 and 8-5.

1-7 A Legally Marketed Predicate Device: **DBC Acupuncture Needles, 510(k) Number. K963300.**

This 510(k) number was submitted by Lhasa Medical, Inc. and the acupuncture needles are manufactured by Dong Bang Medical Co., LTD (DBC). The subject of this application is identical with the DBC acupuncture needles as a predicate device for substantial equivalence (See appendix 8-7, copies of the DBC and the DBC, Dong Bang Acupuncture Needles' labeling).

2. DESCRIPTION OF THE PROPOSED DEVICE

2-1 Statement of 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.” Acupuncture needles have been used for “the general practice of acupuncture” in the United States. The DBC, Dong Bang acupuncture needles have only the intended use and indication for use in labeling for the “general practice of acupuncture,” without any other specific use or treatment.

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution
1. Single use only.
 2. Keep away from high temperatures and humidity.
 3. Do not use if inside package is damaged.
(for bulk) Discard any unused needles in the (open) package after treatment session is complete.

2-2 Device Specifications

2-2-1 Physical Specifications

DBC, Dong Bang acupuncture needles have no visible defects in acupuncture needle body finishing under the magnification of 100 times. Their tips are (b)(4) Product Specifications. The needle body is made of (b)(4) Product Specifications, the needle handle is made (b)(4) and the insertion tube is made (b)(4). The attachment of the needle body to the needle handle is done mechanically with inner hole of needle handle and the part of prominence and depression of the needle body for attachment, length 15mm). Single Pipe Handle Sterile Acupuncture Needles and Pipe Handle Sterile Acupuncture Needles have a pipe type needle handle. Spring Handle Sterile Acupuncture Needles have a spring shape needle handle.

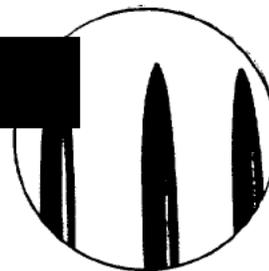
[Drawing of Products]

A. Spring Type

(b)(4) Product Specifications

1. Tip of Needle

(b)(4) Product Specifications



Pine Leaf Shaped Needle Point

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2. Body of Needle

Material: (b)(4) Product Specifications

Length and Thickness: According needle's standard

Prominence and Depression: (b)(4)

(b)(4) Product Specifications

3. Handle of Needle

Material: (b)(4) Product

Length: 20 mm

Outer diameter: ϕ 1.2 mm

Inner diameter: According to size of needle body

(b)(4) Product Specifications

4. Tube for Needle

Material: (b)

Length: According to needle body

Outer diameter: 3.0 mm

5. Bulk Package for 10 Spring Needles and for 5 Pipe Needles

(b)(4) Product Specifications

B. Pipe Type

(b)(4) Product Specifications

1. Tip of Needle

(b)(4) Product Specifications

2. Body of Needle

Material: (b)(4) Product Specifications

Length and thickness: According to needle size

Prominence and Depression: (b)(4)

P d



3. Handle of Needle

Material: (b)(4) Product Specifications

(b)(4) Product Specifications

Length: 20 mm

Outer Diameter: ϕ 1.1 mm

Inner Diameter: According to size of needle body

bf

4. Insertion Tube of Needle
 Material: (b)(4)
 Length: According to needle body
 Inner Diameter: ϕ 3.0 mm
 Outer Diameter: ϕ 2.0 mm

(b)(4) Product Specifications

5. Single Pipe Blister Package
 Case:

(b)(4) Product Specifications

Sterilized Paper

(b)(4) Product Specifications

2-2-2 All Sizes of DBC, Dong Bang Acupuncture Needles

o: The Proposed Acupuncture Needle Sizes

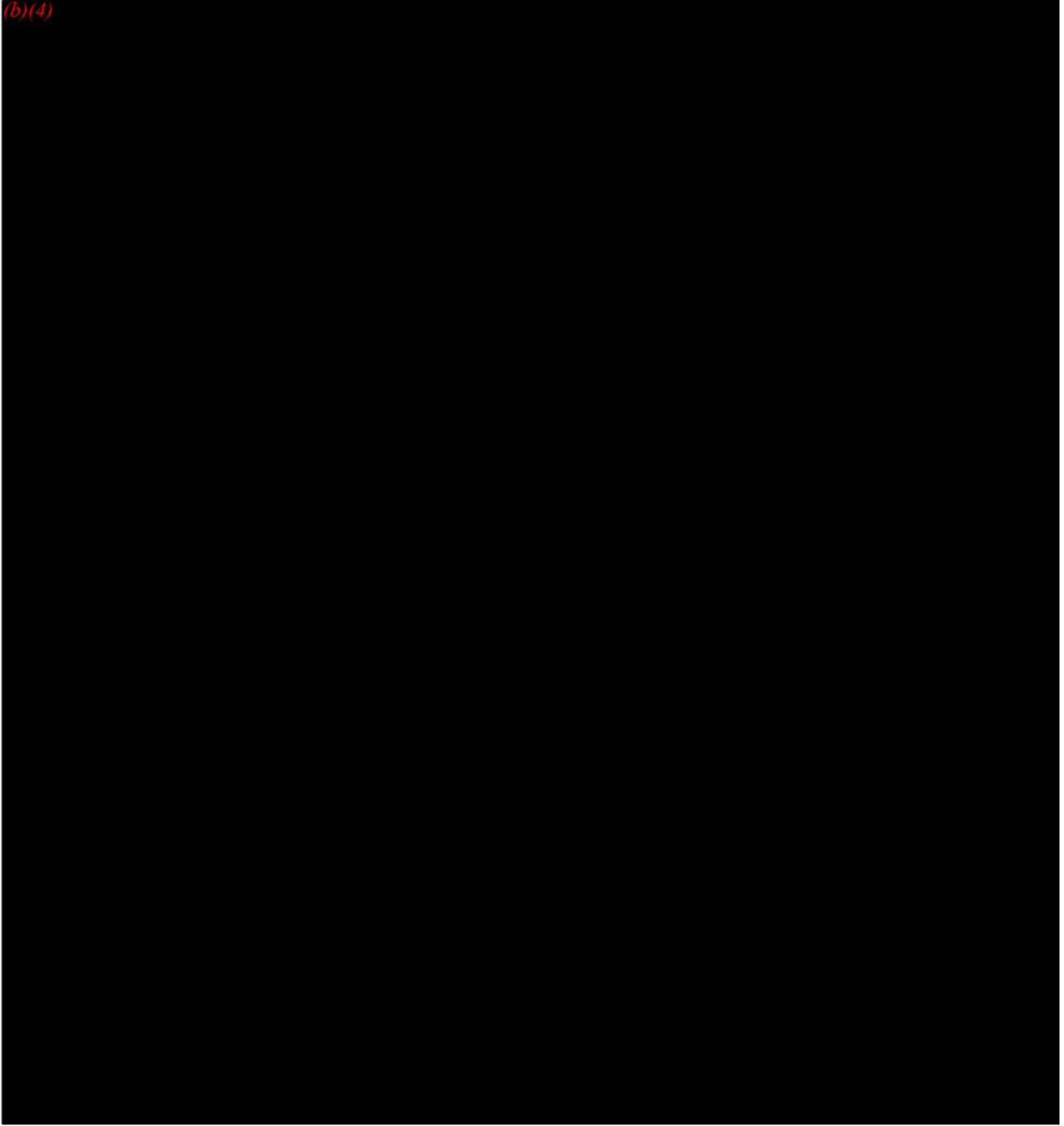
Blade Diameter	Blade Length									
	7 mm	15 mm	30 mm	40 mm	50 mm	60 mm	75 mm	90 mm	120 mm	160 mm
0.16	o									
0.18		o	o	o	o	o				
0.20		o	o	o	o	o				
0.22		o	o	o	o	o				
0.25		o	o	o	o	o				
0.26		o	o	o	o	o				
0.28		o	o	o	o	o				
0.30		o	o	o	o	o	o			
0.35		o	o	o	o	o	o	o		
0.40		o	o	o	o	o	o	o		
0.45		o	o	o	o	o	o	o	o	
0.50		o	o	o	o	o	o	o	o	
0.70						o	o	o	o	o

All sizes are indicated as "(Blade Diameter) mm x (Blade Length) mm."

b1

3. MATERIAL IDENTIFICATION, BIOCOMPATIBILITY AND MECHANICAL TESTING

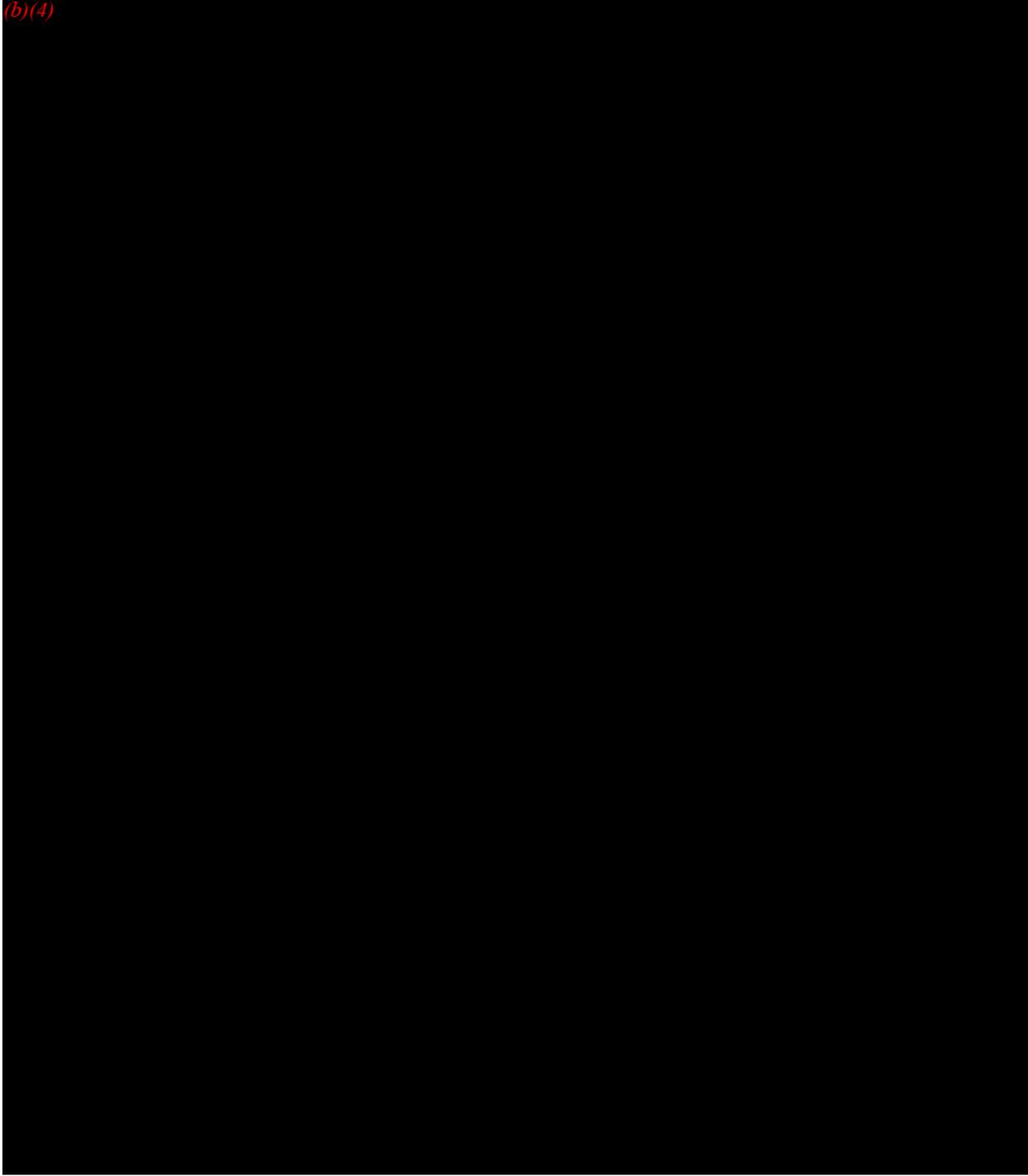
(b)(4)



to b

4. STERILIZATION INFORMATION

(b)(4)



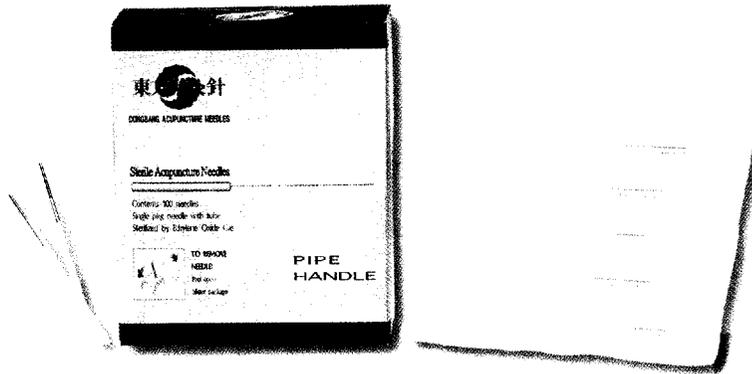
67

5. PROPOSED LABELING

5-1 The Various Types of Proposed Devices: Device and Package Labels

“DBC, Dong Bang Acupuncture Needles” have three types of needle names: (1) “Single Pipe Handle Sterile Acupuncture Needles,” (2) “Spring Handle Sterile Acupuncture Needles,” and (3) “Pipe Handle Sterile Acupuncture Needles” as follows:

[Single Pipe Handle Sterile Acupuncture Needles]



● DBC1-1

{Pipe Blister Needle: Box of 100 Needles: 1 Needle with a Plastic Insertion Tube per Each Sterile(EOG) Sealed Blister Package}

[Spring Handle Sterile Acupuncture Needles]



● DBC1-2

{Spring Bulk Needle: Box of 100 Needles: 10 Needles with a Plastic Insertion Tube per Each Sterile (γ-ray) Sealed Bulk Package}

[Pipe Handle Sterile Acupuncture Needles]



● DBC1-3

{Pipe Bulk Needle: Box of 100 Needles: 5 Needles with a Plastic Insertion Tube per Each Sterile (γ-ray) Sealed Bulk Package}

* Please see samples suggested for labeling (appendix 8-6, #).

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5-2 Package Inserts: Sterile, Disposable Needle, Number and Quantity, and Insertion tube

“Single Pipe Handle Sterile Acupuncture Needles” are individually packaged with a pipe blister needle and a plastic insertion tube per each sterile sealed (EOG) blister package (PET + Sterile Paper). A small box is 100 needles. “Spring Handle Sterile Acupuncture Needles are packaged with 10 spring handle needles and a plastic insertion tube per each sterile (γ -ray) sealed bulk package (non-toxic PET + LLDPE). “Pipe Handle Sterile Acupuncture Needles” are packaged with 5 pipe handle needles and a plastic insertion tube per each sterile (γ -ray) sealed bulk package. These insertion tubes are made of PP. A large box, with 1000 acupuncture needles, is packaged with 10 small boxes as described above (see the above picture and the samples of appendix 8-6, #).

5-3 Size Indication

Sizes vary as mentioned above in 2-2-2. According to blade diameter and blade length, the DBC, Dong Bang acupuncture needles are indicated as “mm x mm” (i.e., 0.20mm x 40mm) by a stamp on the small box and the large box.

5-4 Prescription Statement

DBC, Dong Bang acupuncture needles are labeled as follows:

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States.

- Caution
1. Single use only.
 2. Keep away from high temperatures and humidity.
 3. Do not use if inside package is damaged.

Additionally, for bulk package (10 Spring or 5 Pipe handle needles):
Discard any unused needles in the (open) package after treatment session is complete.

As shown in the attached samples, the label and labeling of DBC, Dong Bang consists of package label, instructions for use, package inserts, and prompts: size, expiration date, sterility, types, guidance for distributor. The subject of this 510(k), the DBC, Dong Bang acupuncture needle has the same intended use as the DBC (K963300) and the same technological characteristics as the DBC.

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6. COMPARISON OF SUBSTANTIAL EQUIVALENCE

6-1 Table of Similarities and Differences

Similarity: o Difference: x

Division	DBC, Dong Bang	DBC	cf. (Dong Bang)
Intended use	o	o	general practice of acupuncture, single use only
Labeling	o	o	the same except trade name and distributor
Design of Device	o	o	fine leaf shaped tip, spring and pipe handle
Specifications	o	o	handle type: spring and pipe
Materials	o	o	18-8 surgical stainless steel wire (sus-304), brass & nickel chromed, PET+LLDPE
Biocompatibility	o	o	stainless steel
Chemical Safety	o	o	non-toxic
Mechanical Safety	o	o	safety tested for shape, bending, twisting, elasticity, and needle handle bond strength
Performance	o	o	qualified practitioner
Radiation Safety	o	o	<25ppm, >25kgy
Standards met	o	o	safety and effectiveness
Sterility	o	o	sterile (γ-ray or EOG for Dong Bang)
Thermal safety	o	o	pyrogen free
Trade name, distributor in labeling	x	x	a new 510 (k) needed for marketing

6-2 Analysis and Information about Safety and Effectiveness

6-2-1 Comparative Analysis between the Two Devices

Acupuncture needles of two trade names are manufactured by the same manufacture, Dong Bang Medical Co., LTD. For the purpose of marketing through a new trade name and distributor, the different specializations are indicated as follows:

	DBC, Dong Bang Acupuncture Needle	DBC Acupuncture Needle
Name	DBC, Dong Bang Acupuncture Needles	DBC
distributor	Morning Star, Dong Bang Acu. Inc.	Lhasa Medical, Inc.

The differences of trade name, guidance for distributor, color and design in package labeling do not affect the intended use or technical characteristics of the acupuncture needles. Instructions for use, package inserts, sterility, types, materials, and physical specializations are the same between the two devices.

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6-2-2 Information about the Two Devices' Safety and Effectiveness

Dong Bang Medical Co., LTD's acupuncture needles of Korea have been imported and sold through commercial interstate distribution to the U.S.A. by Dong Bang USA, Inc. (510(k) number: K972659), Lhasa Medical, Inc. (510(k) number: K963300) since 1988. At this time, no accident or device failure claims have been reported as a result of using the DBC, Dong Bang acupuncture needles of Korea. Dong Bang Medical Co., LTD, DBC bear a "Q"(qualified) mark by which Korea government guarantees needle quality, safety and effectiveness. Dong Bang Medical Co., LTD has 4 technological patent rights by the Office of Patent Administration (OPA) of Korea (see p. 17, Internet Home Page, [http://www. DongBangC.co.kr](http://www.DongBangC.co.kr) of Dong Bang Acupuncture Needles Co.)

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. At this time, we are not aware of any serious or life-threatening accidents involving acupuncture needles. The proposed DBC, Dong Bang Acupuncture Needles as a new trade name for DBC acupuncture needles which are currently being marketed through interstate distribution, offer greater safety, since they are sterile (γ -ray and EOG), single use only, stainless and non-pyrogenic acupuncture needles, as suggested in the above description and sterilization of the device.

The subject of this 510(k) application, DBC, Dong Bang Acupuncture Needles, as a γ -ray or EOG sterile, single use only acupuncture needle, is not only safe, but also meets the physical specifications, biocompatibility, mechanical testing criterion for an acupuncture needle and is effective for the practice of acupuncture as discussed in the preceding chapters.

The proposed Dong Bang, DBC acupuncture needle is safe and effective, non-toxic, non-pyrogenic, painless, uniform, and smooth in insertion. The subject of this 510(k) application, the DBC, Dong Bang acupuncture needle is **identical** to the legally marketed DBC acupuncture needle (K963300).

7. ADVERTISEMENT FOR DONG BANG, DBC PRODUCTS

Dong Bang Medical Co., LTD has activated the commercial advertisements through catalogs, magazines, and Internet Home Page (<http://www.DongBangC.co.kr>).

7-1 Introduction to Dong Bang Medical Co., LTD

Company Information



Since November 24, 1987 with permission No.263 from government, our company has been established to produce disposable needles for medical treatment in traditional oriental hospitals.

With automatical production line, we invented the needle of high technique to reduce the pain of patients with special know-how, which is the first trial in Korea. And with ability to produce 8,000,000 pieces for domestic markets such as Kyunghee Medical Center, Wonkwang Univ. Hospital. And also we are planning to export some products, though it is small quantity, through local branches to foreign markets such as America.

Company History

- 1987. 06 Established Dong Bang Acupuncture, Inc.
- 1987. 11 Permission on manufacturing and treatment of medical instruments from Government (Ministry of Health No.263)
- 1991. 03 Established local branch in China
- 1997. 04 Q mark for guaranteeing the quality
- 1998. 04 Established local branch in the U.S.A.

Employees

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Countries Exported to

America, England, Spain, EU

Regional Offices

MorningStar. DongBang Acupuncture U.S.A., Inc.
 (staff in charge: Ae-Hoe, Kwon)
 1429 Lyndon St.
 S. Pasadena, CA 91030
 E-mail; DBCacup@aol.com
 Tel ; 626-403-5959
 Fax ; 626-403-0128

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7-2 Technology, Certification and Products

TECHNOLOGY

Kinds	Items with permission	No.	The concerned authority	Date
Guarantee for quality	Stainless acupuncture needle	95-057	Korean Life Goods Test Research Institute	1997. 04. 23
Utility Design	XXXXXXXXXX	071693	The Office of Patent Administration (OPA)	1995. 03. 30
Design Registration	XXXXXXXXXX	071398	The Office of Patent Administration (OPA)	1995. 11. 10
Design Registration	XXXXXXXXXX	071397	The Office of Patent Administration (OPA)	1995. 11. 10
Trademark Registration	D B C	297639	The Office of Patent Administration (OPA)	1994. 09. 03

Certifications



Products

* Acupuncture needle:
 Disposable needle (named Blister: single)
 Spring and Pipe needle (sold by bulk),
 Long needle (Gold handle needle),
 Acupuncture needle for palm and many kinds

* Moxa
 Indirect moxa, mini moxa, pipe-shaped moxa, moxa plate, etc.

* Suction Instrument

* Human body shape / the picture of blood fixed places

As shown above, Dong Bang Medical Co., LTD, DBC activates advertises through Internet Home Page, <http://www.DongBangC.co.kr>, Catalogs and "Giuep Nara," the magazine of "The Small and Medium Industry Promotion Corporation."

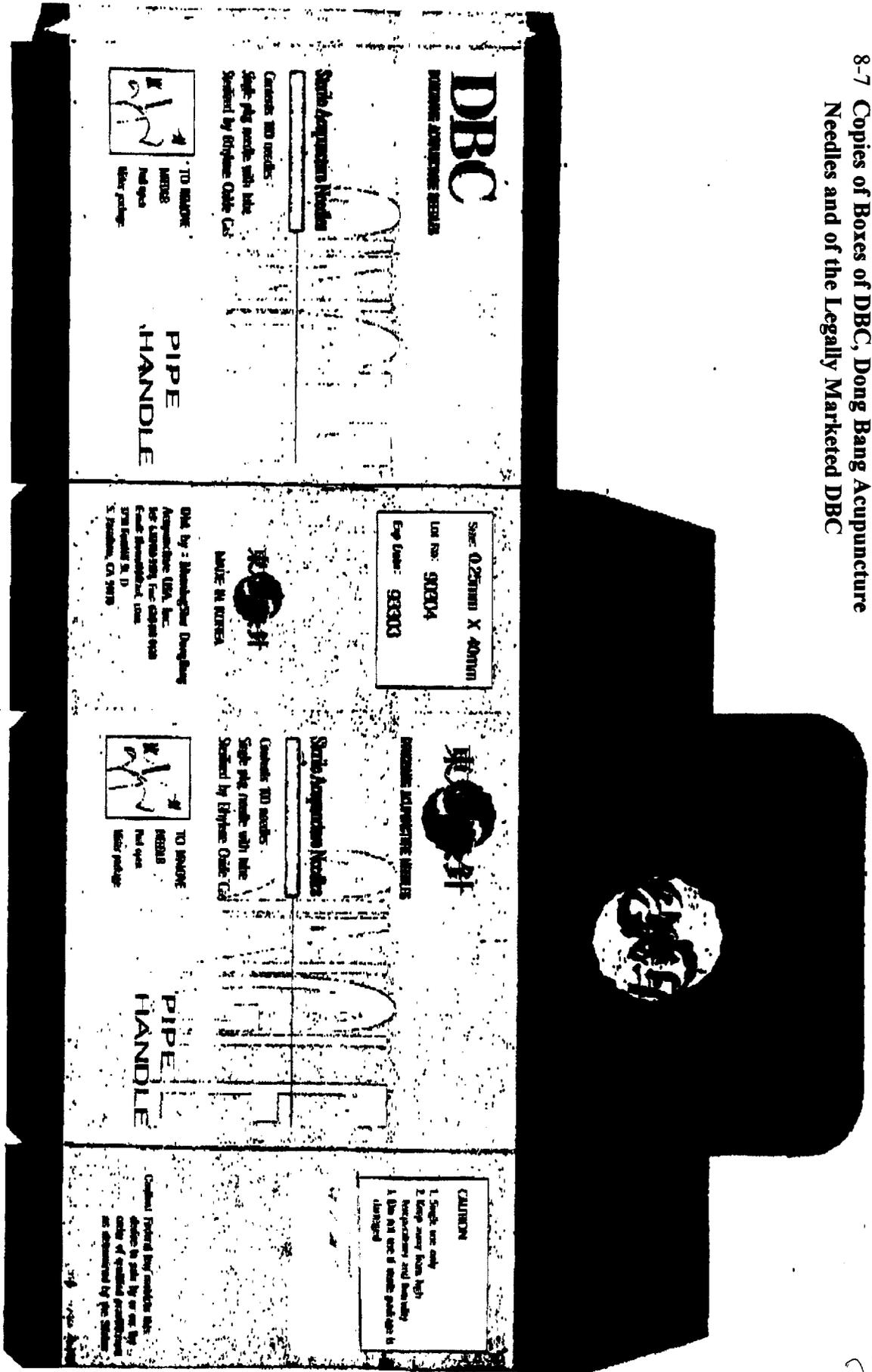
73

8. APPENDIXES

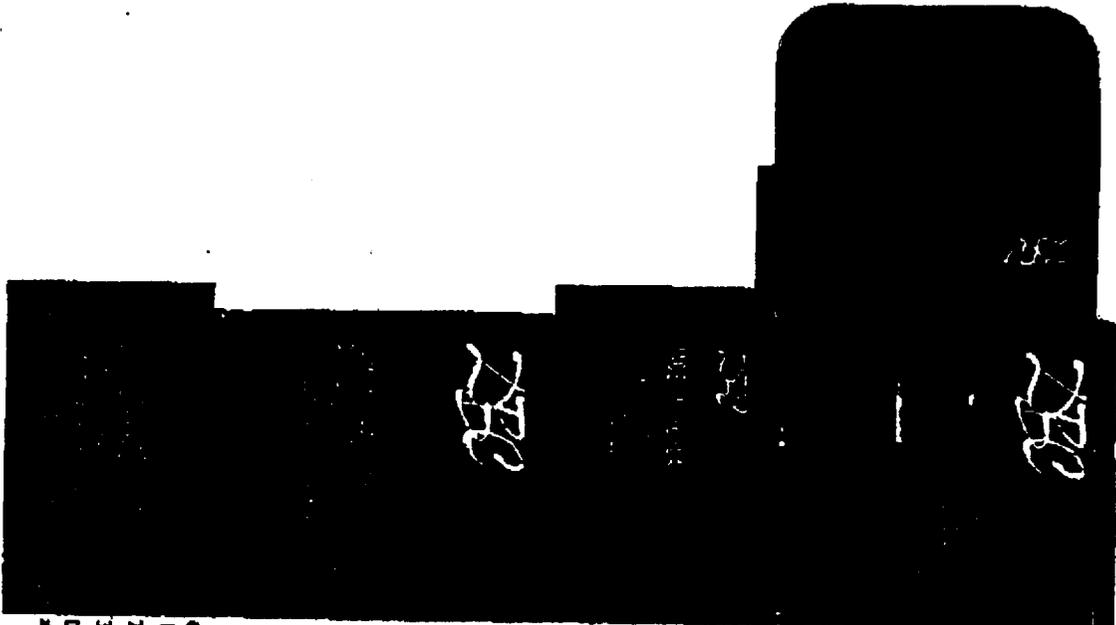
8-1 The Letter of Authorization	19
8-2 510 (k) No (K963300) Submitted by Lhasa Medical, Inc.	20
8-4 Dong Bang Medical Co., LTD's Catalog	21
8-6 DBC, Dong Bang Acupuncture Needle Big Boxes (1000/ea) and Samples	#
8-7 Copies of Boxes of DBC and DBC, Dong Bang Acupuncture Needles	24

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8-7 Copies of Boxes of DBC, Dong Bang Acupuncture
Needles and of the Legally Marketed DBC



24-1



**P
HANDLE**
Sterile Acupuncture Needles

Size 0.20mm X 30mm
Lot No. 90304

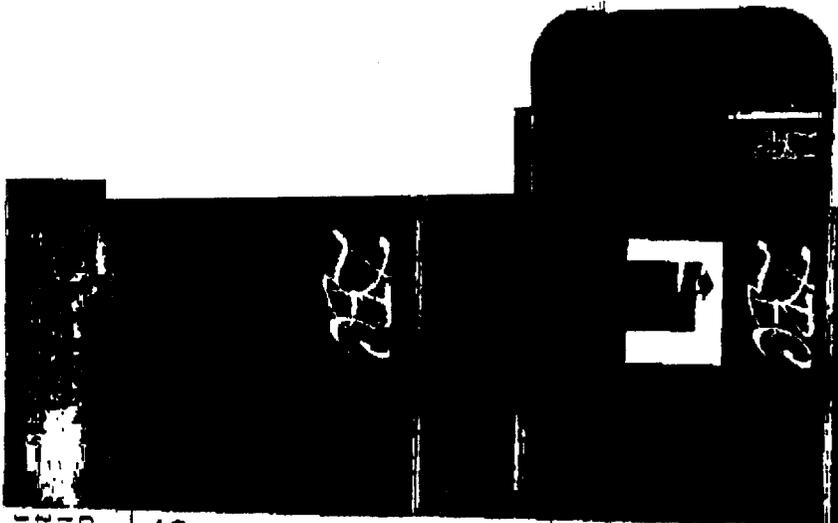
**P
HANDLE**
Sterile Acupuncture Needles



- CAUTION**
1. Single use only
 2. Keep away from high temperatures and humidity
 3. Do not use if inside package is damaged
- Use and any other needles in the (type) package after examination system is complete.

24-3

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HANDLE

Sterile Acupuncture Needles

Size: 0.25mm X 40mm

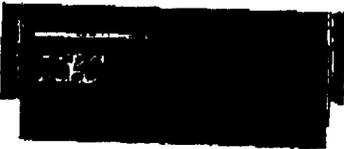
Lot No. 90304

HANDLE

Sterile Acupuncture Needles

CAUTION

- 1. Single use only
- 2. Keep away from high temperatures and humidity
- 3. Do not use if outer package is damaged



24-4

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24-5

Size: 0.30mm X 50mm

Lot No: 90304



MADE IN INDIA
Wiss-Jelham Medical, Inc., Seoul, IN
1-800-372-8715

INDIA
Acupuncture Needles

Contents 100 needles
Single pkg needle with tube
Sterilized by Gamma Ray



NO REMOVE
NEEDLE:
Push open
Mirror package

PIPE
Sterile Acupuncture

Contents 100
Single pkg needle
Sterilized by Gamma

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) *Rafaela Cruz*

Subject: 510(k) Number *K 990328 / ~~SA~~*

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO
 Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO
 Is this device subject to the Tracking Regulation? YES NO
 Was clinical data necessary to support the review of this 510(k)? YES NO
 Is this a prescription device? YES NO
 Was this 510(k) reviewed by a Third Party? YES NO
 Special 510(k)? YES NO
 Abbreviated 510(k)? YES NO

Incomplete Information
Submission back on hold

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

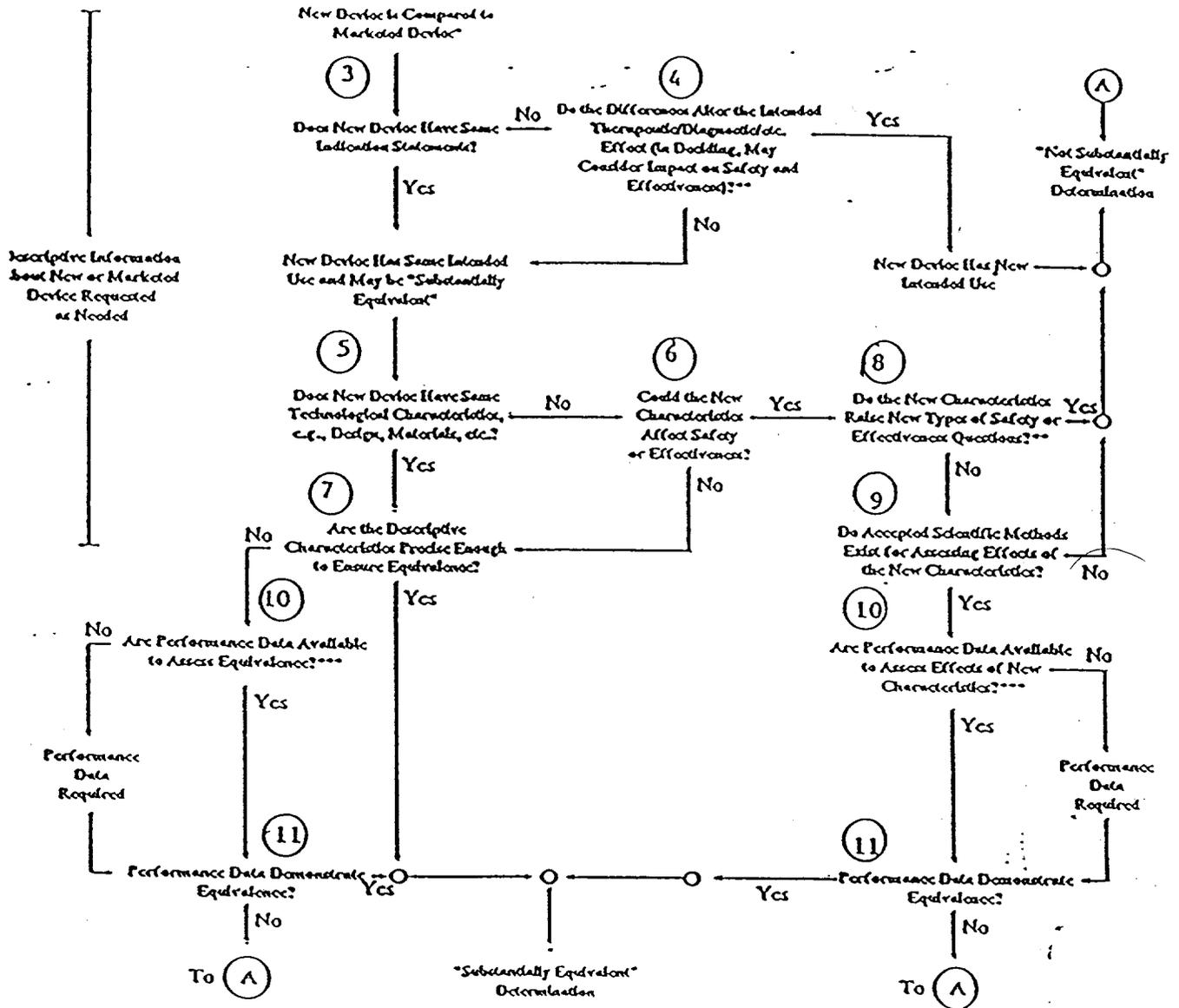
Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: *Rafaela Cruz* *CANDB3* *3/12/07*
 (Branch Chief) (Branch Code) (Date)

Final Review: _____ (Date)
 (Division Director)

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Mr. Ae-Hoe Kwon
Morning Star, Dong Bang Acupuncture U.S.A., Inc.
1429 Lyndon Street
South Pasadena, California 91030-3811

Re: K990328
Trade Name: DBC, Dong Bang Acupuncture Needles
Dated: January 28, 1999
Received: February 2, 1999

Dear: Mr. Ae-Hoe Kwon:

We have completed an administrative review of your section 510(k) Premarket Notification (510(k)) of intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold for 30 days pending receipt of the additional information that was requested in a telephone conversation with the Office of Device Evaluation. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain

Handwritten signature or initials in black ink, possibly reading "fz".

Page 2 - Mr. Ae-Hoe Kwon

clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Ms. Irene Naveau at (301) 594-1287. If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or its toll free number (800) 638-2041, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely,



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

Enclosures

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1K990328/ST A2

Ae-Hoe Kwon
MorningStar, DongBang 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

FDA/CDRH/OCE/DMC
FEB 22 2 44 PM '99

Feb. 13, 1999

FDA/CDRH
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Ref.: 510(k) Number: K990328
Device Name: DBC, Dong Bang Acupuncture Needles

Dear Ms. Marjorie Shulman,

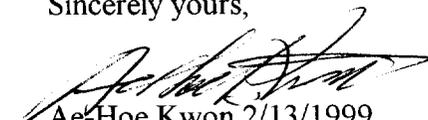
This is in response to the second letter dated on Feb. 04, 1999. With an air of concern for missing, I am sending the same "Indication For Use" again.

I thank for a correction of the product name on the first letter.

Dong Bang acupuncture needles (DBC acupuncture needles) have been imported by other importers since 1988 {510(k) 963300 submitted by Lhasa Medical, Inc., and K972659 submitted by Dong Bang USA}. My shipments have been detained by L. A. FDA custom over 2 months because these 510(k) numbers belong to the special importers.

Thank you very much.

Sincerely yours,


Ae-Hoe Kwon 2/13/1999

SK
60

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510(K) NUMBER (IF KNOWN): K990328

DEVICE NAME: DBC, DONG BANG ACUPUNCTURE NEEDLES

INDICATIONS FOR USE

The Dong Bang Acupuncture Needles Co., DBC clearly indicates in aspect of performance of sale and treatment {As requested by 21 CFR 807.87(d)} on the labeling as follows:

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States

The Dong Bang Acupuncture Needles Co., DBC shows the “indications for use” (Warning, Precautions and Maintaining Device Effectiveness) according to the “Medical Device Labeling Suggested Format and Content Draft” issued by FDA on April 25, 1997 and “Acupuncture Needles Status Changed: T96-21, April 1, 1996, <http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html>” as follows:

- Caution**
- 1. Single use only**
 - 2. Keep away from high temperatures and humidity**
 - 3. Do not use if inside package is damaged.**
- Discard any unused needles in the (open) package after treatment session is complete.**

With regard to “indications for use,” DBC, Dong Bang acupuncture needle labeling, the subject of this 510(K) application has the same intended use and has the same technological characteristics as the legally marketed DBC {510 (k) K963300} acupuncture needles supplied by the same manufacture, DBC, Dong Bang Acupuncture Needles Inc. On labeling of indications of use, please see Appendixes #, out-boxes labeling for 1000pcs (In-boxes: 100pcs x 10).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Date: 2/17/99
Reviewer(s) - Name(s) Irene Nareau

Memorandum

Subject: 510(k) Number K 990328

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

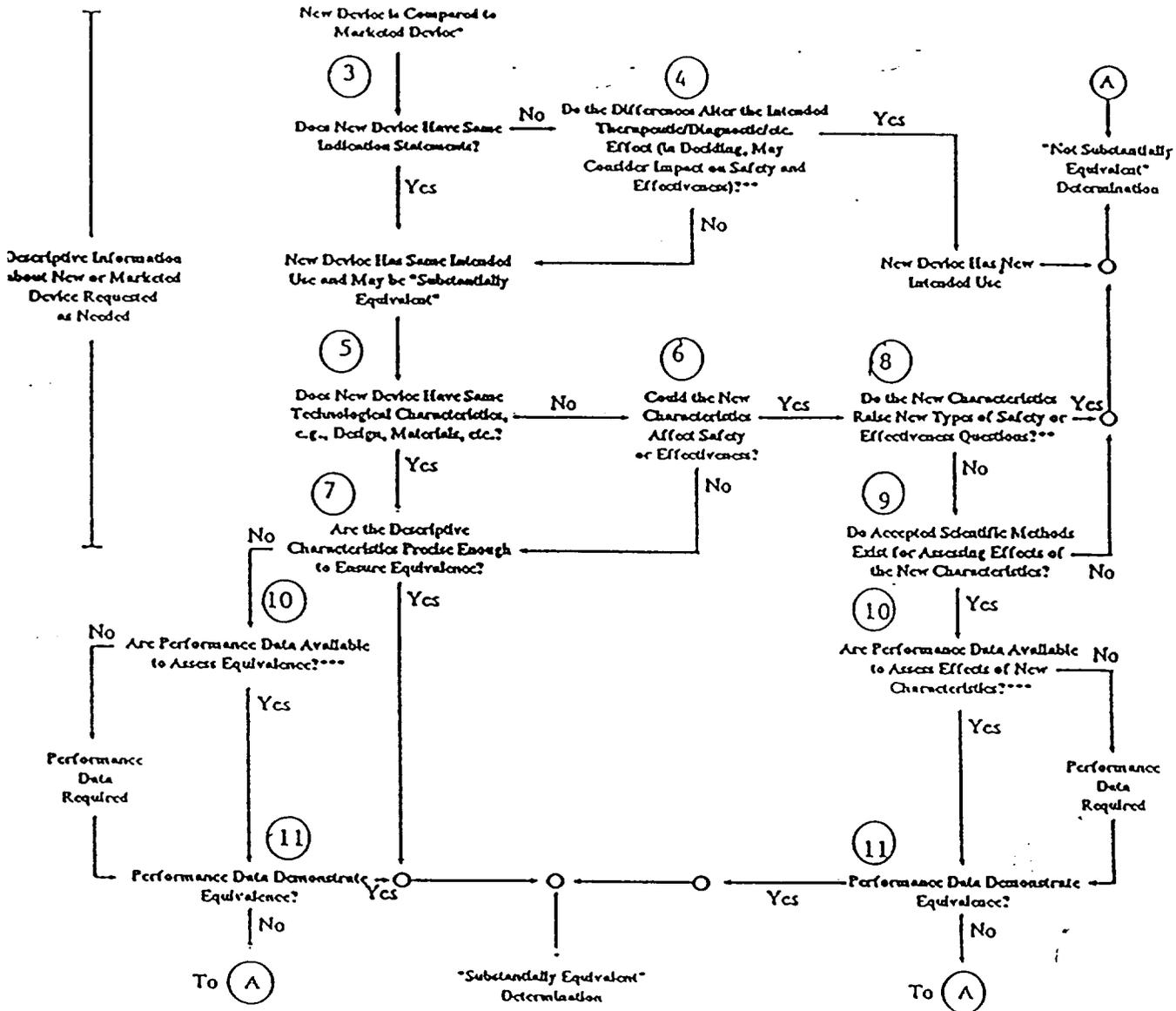
Additional Product Code(s) with panel (optional):

Re: Silvaco Circuit 614013 2/19/99
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Division of Dental, Infection Control, and General Hospital Use Devices
(DDIGD)

Screening Checklist for Premarket Notifications [510(k)s]

ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: DBC, Dong Bang Acupuncture Needles K990328	
Submitter Name: Morning Side, Dong Bang Acupuncture USA Inc.	
General Content of a 510(k)	MISSING INFORMATION
<p>1.* <u>General Information:</u> a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address.</p> <p>COMMENT: Please state if the subject of this 510k is a new device or a modification of a legally marketed device.</p>	See comment.
<p>2.* <u>Safe Medical Device Act of 1990 Requirements:</u> a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement</p> <p>COMMENT: The Indications for Use statement that you recently submitted include extraneous information that is not appropriate for this statement. Please refer to the Introduction in the enclosed Acupuncture Checklist regarding intended use and indications for use. (These uses are identical.)</p> <p>Please revise the content of your Summary. Refer to the enclosed information (Code of Federal Regulation-section 807.92.</p>	See comment.
<p>3.* <u>Proposed Labeling:</u> a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device.</p> <p>COMMENT: Please include, in the labeling, sizes for the acupuncture needles (length and gauge) in inches and in millimeters. Because some of your needles are packaged in bulk, a statement for bulk packaging</p>	See comment.

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<p>should be included in the label. Refer to enclosed Acupuncture Checklist. The promotional information that you have included (pg.7) indicates that your device is for electroacupuncture and moxubution. The table on Pg. 19-7 also includes references magnetic needles. Please note that Class II acupuncture needles are cleared for general purpose usage only. Please explain. It is not necessary to submit boxes to demonstrate your labeling. (pgs. 8-9) Please re-submit your labeling by making copies of the boxes, and place them on another page. Please translate any materials that you have submitted.</p>	
<p>4.* <u>Description of Device (or modification)</u>: diagrams, engineering drawings, or photographs.</p> <p>COMMENT: Your narrative device description is incomplete. Please describe your device as outlined in the enclosed checklist. Please include all sizes, needle surface finishing, needle handle, insertion needle materials, etc. Refer to checklist.</p>	<p>See comment.</p>
<p>5.* <u>Comparison Information</u>: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness.</p> <p>COMMENT: Are you a member of the acupuncture coalition? If you are a member of the coalition, you need not compare your device with a legally marketed acupuncture needle. With how many legally marketed devices do you wish to compare your acupuncture needle? Please revise your comparison table by being more specific in your comparison. Please provide a statement to demonstrate the similarities and differences between your device and its predicate. Please also provide an analysis of the comparable safety and effectiveness of your device.</p>	<p>See comment.</p>
<p>6. <u>Biocompatibility Data</u>: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use.</p> <p>COMMENT:</p>	<p>N/A</p>
<p>7. <u>Sterilization Information</u>: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method.</p> <p>COMMENT: Please provide, for your device, the method of sterilization, the validation method, the method of determining pyrogenicity, packaging, and sterility assurance level. If the device is gamma irradiated, provide the dosage of radiation. If the device is sterilized with ethylene oxide, please provide the</p>	<p>See comment.</p>

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<p>residue levels for ethylene oxide, ethylene chlorohydrin, and ethylene glycol. Refer to enclosed sterilization information.</p>	
<p>8. <u>Software Validation & Verification</u>: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification.</p> <p>COMMENT:</p>	<p>N/A</p>
<p>9. <u>Information Recommended in FDA Guidance</u>: There is a FDA guidance document for this device that recommends additional data.</p> <p>COMMENT:</p>	<p>N/A</p>
<p>10. <u>Kit Information</u>: see attachment if this device is a kit.</p> <p>COMMENT:</p>	<p>N/A</p>

In addition, please provide the results of any testing that has been conducted on your acupuncture, i.e., buckling and stiffness tests. Please provide the results of bond strength testing between the needle and the handle.

We are unable to complete an administrative and substantive review of your 510(k) submission for this device because of major deficiencies. I am enclosing our Acupuncture Needles Checklist and other information sheets to guide you in submitting additional information for your device.

I am available to discuss this letter with you by telephone-Monday through Friday-10: 00AM to 2:30 PM (Eastern Time). Following your review of the letter and additional information, please call me at (301) 594-1287, extension 175, and I will try to be of assistance to you.

Irene Naveau 4/16/99

Irene Naveau

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Acupuncture Needles 510(k) Checklist, p. 1

DRAFT

510(k) CHECKLIST FOR ACUPUNCTURE NEEDLES

August 13, 1996

510(k) #: K 990328
Date: 2/16/99
Sponsor: Morning Side, Dong Bang Acupuncture U.S.A. Inc.
Proprietary Name: DBC, Dong Bang Acupuncture Needles
Contact: Ae-Hoe Kwon
Telephone: (626) 403-5959
Fax: (626) 403-0128

Introduction: Summary of the March 29, 1996 Reclassification Order for Acupuncture Needles (Reclassification Order)

Acupuncture Needles are defined (future 880.5580 in the Code of Federal Regulations (CFR)) as "devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states". Acupuncture needles are required to be labeled "For single use only" and to have the prescription statement (21 CFR 801.109(1)(b)) "Caution: Federal law restricts this device to sale by or on the order of a qualified practitioner of acupuncture as determined by the states". They must be made of stainless steel and be sterile.

The intended use, which is in the Reclassification Order (and future CFR) definition of acupuncture needles, and the indications for use, which is for any more specific use, are the same for acupuncture needles that are labeled for the general practice of acupuncture, i.e., to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. Premarket notification (510(k)) submissions for acupuncture needles labeled for any other specific use or treatment than for the general practice of acupuncture must contain documentation



Acupuncture Needles 510(k) Checklist, p. 2

to support that specific use or treatment in the form of valid scientific evidence defined in the CFR in 860.7(c)(2).

For 510(k) submission to be filed for review, the following informational requirements **must** be present: Cover Letter General Information, Administrative Requirements, Description of the Device, Comparison to a Legally Marketed Device, Labeling, and Device Specifications, including Physical Specifications, Material Identification, Biocompatibility, Mechanical Testing, and Sterilization Information. If **any** of these major types of information required in a 510(k) submission is missing, the 510(k) is deemed Refuse to Accept (RTA), and the submission is placed on hold until the missing information is submitted to complete the file. Some types of information, such as administrative information, type of stainless steel, incomplete sterility information, and clarifications on information in the submission may be received by fax **only** if requested by an agency reviewer. Faxed information must then be followed up with a hard copy of the requested information sent to the ODE Document Mail Center.

I. Cover Letter General Information

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Device trade or proprietary name
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Device common name: acupuncture needles
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Establishment registration number
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Classification Panel: 80 (for the General Hospital and Personal Use Devices Panel)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Procode: MQX (for agency tracking)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Class of the device: II
<input type="checkbox"/>	<input type="checkbox"/>	Action taken to comply with Section 514 of the Act (not applicable (NA) for acupuncture needles)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Purpose of the submission (either for a new or modified device)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Equivalence statement (a statement how the device is similar to and different from other acupuncture needles)

Acupuncture Needles 510(k) Checklist, p. 3

- Address of manufacturing site
- 510(k) Applicant name, address, and telephone and fax numbers
- Contact name, address, and telephone and fax numbers, if different from the applicant

II. Administrative Requirements: These statements must be in the required format, signed and dated. There is a required form for the Indication for Use Statement. The Truthful and Accuracy Statement and 510(k) Statement require specific wording which is available from the agency. The 510(k) Summary must be on a separate sheet of paper and be titled "510(k) Summary".

- | Yes | No | |
|-------------------------------------|--------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Indications for Use Statement <i>Incomplete! Needs to be on a separate sheet.</i> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Truthful and Accuracy Statement (21 CFR 807.87) |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 510(k) Summary (21 CFR 807.92) or Statement (21 CFR 807.93) <i>Summary needs to be revised to reflect description, etc. See CFR section 807.92 (enclosed)</i> |

III. Description of the Device

- | Yes | No | |
|-------------------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | State the intended use(s) for the device. For general purpose acupuncture needles, the intended use is for the practice of acupuncture by qualified practitioners as determined by the states. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Sample |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Incomplete</i> Provide a brief narrative description of the device; this may not be needed if specifications are adequate and/or a sample is provided |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Provide labeled diagrams, engineering drawings or photographs of the acupuncture needles and any insertion tubes and needle holders, if applicable; this may not be needed if specifications are adequate and/or a sample is provided |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Packaging: individually and/or bulk |

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Acupuncture Needles 510(k) Checklist, p. 4

IV. Comparison to a Legally Marketed Device

Yes No

Sponsor is a member of the Acupuncture Coalition; if yes, then identification of a predicate device and comparative information are not needed

Identify a legally marketed device(s) to which substantial equivalence is claimed, including its 510(k) number if known, labeling, and complete description of it. *Seven are identified by number. SE to how many?*

Compare your acupuncture needles to the legally marketed device, including the similarities and differences in its intended use, labeling, specifications, materials and any performance data (bench, animal, or clinical data) in a tabular format
Incomplete

Provide an analysis of the comparable safety and effectiveness of your device and the legally marketed device

V. Labeling: Copies of the proposed labels for the inner and outer packaging, any instructions for use, and any advertisements (promotional materials)

Yes No

Device labels, including the following:

Description: Acupuncture Needles

Size: length in inches/mm and gauge in inches/mm/French

Sterile

Quantity

Number of needles in bulk packaging, if applicable

Prescription statement: "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States".

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Acupuncture Needles 510(k) Checklist, p. 5

Statement: "For single use only"

Statement for bulk packaged acupuncture needles: "Discard any unused needles in bulk packages after treatment session", not applicable for individually packaged acupuncture needles

General labeling requirements 21 CFR 810, manufacturer's, importer's or US distributor's name and address

Statement: Made in (name of country)

Pyrogen free

Directions for use, if applicable

Promotional materials, if available

*Review materials w/ sponsor
Translation needed.*

VI. Device Specifications

A. Physical Specifications

Yes No

All sizes: lengths in inches/mm and gauges in inches/mm/French

Needle body surface finishing: under magnification of 100X, there shall be no visible defects

Tip shape

Needle handle: dimensions and method of attachment (chemical, mechanical, heat, or other method), if applicable

Insertion tube, if applicable *material?*

Needle dispenser or holder design and material, if applicable

B. Material Identification

Yes No

Identify the surgical grade stainless steel material specification: for example, Class 3

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Acupuncture Needles 510(k) Checklist, p. 6

Austenitic Stainless Steel per ASTM F 899 - 94, Type 304; if not per ASTM F 899 - 94, provide the complete material specification, including the per cent of chromium and nickel

- Identify the material specification of the needle handle, if applicable
- Identify the adhesive, cement, or other chemical bonding agent used to attach the needle handle to the needle, if applicable
- Identify the insertion tube material, if applicable
- Identify the needle dispenser or holder material, if applicable
- Identify the lubricant used, if applicable

C. Biocompatibility: Stainless steel biocompatibility can be established in one of four ways: 1. use of a surgical grade stainless steel needle material per ASTM F 899 - 94 or its equivalent, 2. certification that the stainless steel is **identical** to that of legally marketed acupuncture needles, 3. valid scientific evidence that the stainless steel is identical that of other devices intended for percutaneous, short-term (<30 days) implantation, or 4. biocompatibility testing results in accordance with the FDA-modified Part 1 of International Standard ISO-10993, "Biological Evaluation of Medical Devices".

Yes No

Stainless steel

- ASTM F 899 - 94 or its equivalent
- Certification statement of identical materials
- Valid scientific evidence of an identical material as in other devices intended for percutaneous, short-term (<30 days) implantation
- Biocompatibility testing results in accordance with the FDA-modified Part 1 of International Standard ISO-10993

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Acupuncture Needles 510(k) Checklist, p. 7

Other materials, if applicable

- Needle handle
- Lubricant
- Other(s)

D. Mechanical Testing

Yes No

- Needle to handle bond strength of at least 1 kilograms (2½ pounds or 0.102 newton), if applicable
- Other testing, such as buckling/stiffness tests for centrally loaded acupuncture needles, etc

E. Sterilization Information

Yes No

- Sterilization method: radiation or ethylene oxide or steam
- Sterilization validation method per AAMI sterilization guidelines or equivalent processes, such as an EN method
- Sterility assurance level (SAL), at least 10⁻⁶
- If radiation, specify the dose
- If ethylene oxide, provide the residues levels (per 1978 FDA proposed rule for devices contacting blood: not to exceed 25 ppm ethylene oxide, 25 ppm ethylene chlorohydrin and 250 ppm ethylene glycol or those set forth in an equivalent guideline or standard
- Pyrogenicity method, USP LAL or rabbit or an equivalent method
- Packaging used to maintain sterility

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Acupuncture Needles 510(k) Checklist, p. 8

VII. Any other concerns

_____ Explain

Overall Filing Evaluation:

_____ Complete for review

_____ Minor clarification(s) and/or administrative information needed which can be obtained by telephone and fax

Major information deficiencies, such as labeling, physical specifications, material identification and biocompatibility, sterilization information

Comments and Actions:

Contact Ae - Hae Kwon via telephone to review checklist and discuss deficiencies of PTA letter sent to sponsor

Recommendation:

Refuse to Accept for Filing
 Accept for Filing

_____ Call sponsor/contact for clarification, administrative statements, minor information requests

_____ Hold after sending or faxing deficiencies

_____ SE

Srene Naveau
General Hospital Devices Branch
Reviewer, Signature and Date

(301)-594-1287
Telephone Number

(310)-480-3002
Fax Number

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K990328/A1

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

1429 Lyndon St.

S. Pasadena, CA 91030-3381

Tel: 626) 403-5959, Fax: 626) 403-0128, E-mail: KwonAH@aol.com

Feb. 8, 1999

FDA/CDRH
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED

FEB 10 1 54 PM '99

FDA/CDRH/OCE/DMC

Re: 510(k) Number: K990328
Device Name: DBC, Dong Bang Acupuncture Needles

This is in response to your letter dated on Feb. 03, 1999. Thank you for your prompt answer.

I included a special chapter 3, page 6: "Statement of indications for use" on 510 (k) 990328 for DBC, Dong Bang acupuncture needles, but I did not provide on a separate page. According to your guidance, I am sending "Indication For Use."

Additionally, I would like to request a correction of the product name on your letter as follow:

Product: DBCC, DONG BANG
ACUPUNCTURE NEEDLES

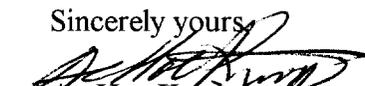
→ : DBC, DONG BANG
ACUPUNCTURE NEEDLES

Please delete one "C" of "DBCC."

This same acupuncture needles which have been imported by other importers since 1988 {510(k) 963300, 972659} have been detained by L. A. FDA custom over 2 months because these 510(k) numbers belong to the special importers.

I beg you an "expedited review." Only I pray for it to God. The part of the needles must be sent to Russia with Christian medical mission team.

Sincerely yours,


Ae-Hoe Kwon

SK
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510(K) NUMBER: K990328

DEVICE NAME: DBC, DONG BANG ACUPUNCTURE NEEDLES

INDICATIONS FOR USE

The Dong Bang Acupuncture Needles Co., DBC clearly indicates in aspect of performance of sale and treatment {As requested by 21 CFR 807.87(d)} on the labeling as follows:

Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States

The Dong Bang Acupuncture Needles Co., DBC shows the indications (Warning, Precautions and Maintaining Device Effectiveness) for use according to the "Medical Device Labeling Suggested Format and Content Draft" issued by FDA on April 25, 1997 as follows:

- Caution**
- 1. Single use only**
 - 2. Keep away from high temperatures and humidity**
 - 3. Do not use if inside package is damaged.**
- Discard any unused needles in the (open) package after treatment session is complete.**

With regard to "indications for use," DBC, Dong Bang acupuncture needle labeling, the subject of this 510(K) application has the same intended use and has the same technological characteristics as the legally marketed DBC (K963300) acupuncture needles (See Appendixes #, Out-boxes labeling for 1000 (In-boxes: 10x100).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <i>DBC Dong Bang Acupuncture Needles</i>		K990328		
Submitter (Company): <i>Morning Star, Dong Bang Acupuncture U.S.A., Inc.</i>				
Items which should be included (circle missing & needed information)	SPECIAL	ABBREVIATED	TRADITIONAL	✓ IF ITEM IS NEEDED AND IS MISSING
	YES NO	YES NO	YES NO	
1. Cover Letter clearly identifies Submission as:				
a) "Special 510(k): Device Modification"			✓	
b) "Abbreviated 510(k)"				
c) Traditional 510(k)				
	GO TO # 2,4	GO TO # 3,4,5	GO TO # 4,5	
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS				✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA	YES	NO	
	SPECIALS	ABBREVIATED	TRADITIONAL	AND IS MISSING
	YES NO	YES NO	YES NO	
a) trade name, classification name, establishment registration number, device class			✓	
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator			
c) identification of legally marketed equivalent device	NA		✓	
d) compliance with Section 514 - performance standards	NA		✓	
e) address of manufacturer			✓	
f) Truthful and Accurate Statement			✓	
g) Indications for Use enclosure			✓	
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)			✓	
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)				
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals			✓	
k) Proposed Labeling:			✓	
i) package labeling (user info)			✓	
ii) statement of intended use			✓	
iii) advertisements or promotional materials				
i) MRI compatibility (if claimed)				
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:			✓	
i) Labeling			✓	
ii) intended use			✓	
iii) physical characteristics				
iv) anatomical sites of use				
v) performance (bench, animal, clinical) testing	NA			
vi) safety characteristics	NA			
m) If kit, kit certification				
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) STATEMENT - INTENDED USE AND INDICATIONS FOR			* If no - STOP not a special	

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							102

iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No

Reviewer: _____

Date: FEB - 5 1999

Concurrence by Review Branch: _____

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REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 03, 1999

MORNING STAR, DONG BANG ACUPUNCTURE 510(k) Number: K990328
1429 LYNDON ST. Received: 02-FEB-1999
SOUTH PASADENA, CA 91030 Product: DBCC, DONG BANG
ATTN: AE-HOE KWON ACUPUNCTURE NEEDLES

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

K990328

510(k) NOTIFICATION

**Reason for Submission: Marketing of Acupuncture Needles
Which Have Been Marketed by Other Importers
(i.e., K963300): Request for Expedited Review
on Low and Moderate Risk, and
in Detention of Needles (L. A.)**

Device Classification Name: Needle, Acupuncture, Single Use

510(k) Number: K _____.

Device Name: DBC, Dong Bang Acupuncture Needles

Applicant: 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,

Contact: Ae-Hoe Kwon

Product Code: MQX

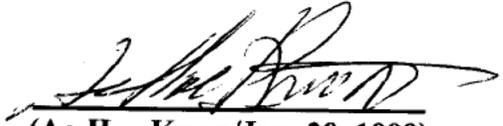
Class: II

Medical Specialty (panel): General Hospital (21 CFR Part 880)

Manufacture: [Redacted] e (b)(4) [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

RECEIVED
FEB 2 2 11 PM '99
FDA/CDRH/OCE/DHC

Date Submitted: January 28, 1999


(Ae-Hoe Kwon/Jan. 28, 1999)

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24
17

5/1
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¹ **Dong Bang Acupuncture Needles Co., or DBC, is the same company.** DBC is the brand name and abbreviation of Dong Bang Acupuncture Needles Co., and DBC has been patented to Keun-Sik Kim (president) by Korean Patent Bureau since 1994.

MorningStar, DongBang 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

JANUARY 28, 1999

PRE-MARKET NOTIFICATION 510 (K) SUMMARY
{ As Required by 21CFR 807.929(c) }

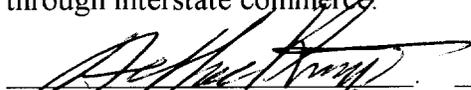
Acupuncture needles (**Needle, Acupuncture, Single Use: Class II; MQX**) are defined as devices **intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.** Acupuncture needles have been used for the general practice of acupuncture in the United States for over 30 years.

At this time, we are not aware of any serious or life-threatening accidents 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 are currently being marketed through interstate distribution (i.e., DBC: 510(k) K963300) offer greater safety, since they are sterile, single use only acupuncture needles.

The subject of this 510(k) application, "**DBC, Dong Bang acupuncture needle,**" is a γ -ray sterile, single use only acupuncture needle. The DBC, Dong Bang acupuncture needle meets the general specifications and criteria for an acupuncture needle and is effective for the practice of acupuncture.

This DBC, Dong Bang acupuncture needle is manufactured in Korea and has been imported and sold through interstate commerce in the USA **since 1988** under the FDA labeling restrictions of "Caution: Investigational device limited by U.S. law to investigational use," or "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the State"(since Apr. 1, 1996). Since 1988, no accidents or device failure claims have been reported as a result of using the DBC, Dong Bang brand acupuncture needle.

In conclusion, based on the information provided with this 510(k) application, the DBC, Dong Bang brand acupuncture needle meets the criteria for 510 (k) acceptance. The DBC, Dong Bang brand acupuncture needle is equivalent not only to acupuncture needles which were in commercial distribution prior to May 28, 1976, but also to other legally marketed devices, the **DBC (K963300)** or the **HaengLim SeoWeon (K961677)** brand needles which are currently being sold through interstate commerce.

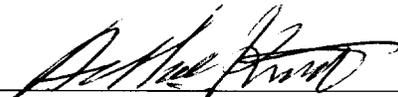
 1/28/99
Ae-Hoe Kwon, President Date

Premarket Notification 510(k) Number: K

NO

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as “regional office staff in charge,” importer and the US designated agent of Dong Bang Acupuncture Needles Co., DBC, and president of Morning Star, Dong Bang Acupuncture U. S. A., Inc., I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Ae-Hoe Kwon

(Typed Name)

01/28/1999

(Dated)

K

(Pre-market Notification [510(k)] Number)



1. THE NAME, CLASS, AND ESTABLISHMENT REGISTRATION NUMBER OF DEVICE

1-1. The Name of Device

- 1-1-1 Trade name: **DBC, Dong Bang Acupuncture Needles**
- 1-1-2 Common or usual: **Acupuncture Needles**
- 1-1-3 Classification name: **Needle, Acupuncture, Single Use**

1-2 The Class of Device

- 1-2-1. Needle, Acupuncture Single Use: **Class II**
 - The FDA has announced that acupuncture needles have been reclassified from Class III to Class II (1/April/1996, <http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html>).

1-2-2 Medical Specialty (panel): **General Hospital** (21 CFR Part 880)

1-2-3 Product Code No: **MQX**

1-3 The Establishment Registration Number

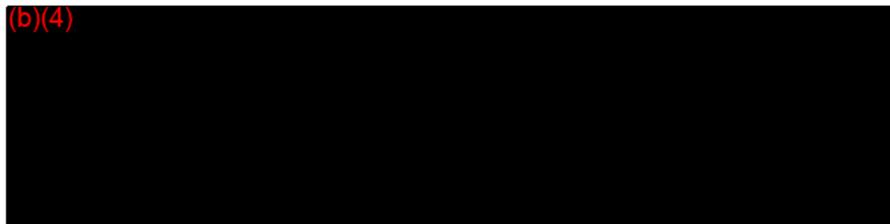
1-3-1. Manufacture: Dong Bang Acupuncture Needles, Inc. (DBC)

* FDA Registration No: **8040810** (since 1988)

* Device Listing No: **B 008479**

* Address of Manufacture:

(b)(4)



1-3-2 Importer, Morning Star, Dong Bang Acupuncture U.S.A., Inc.:
Regional Office/the Sole US Agent designated by DBC
(see Appendixes 8-1)

- FDA Registration Form Operation and owner ID: (b)(4)
- LA Regional Registration Form No: (b)(4)



2. PERFORMANCE STANDARDS: ACTION TO ANY APPLICABLE FDA SPECIAL CONTROLS FOR CLASS II {21 CFR807.87(d)}

Acupuncture Needles (Needle, Acupuncture, Single Use: Class II; MQX) are defined as “**devices intended to pierce the skin in the practice of acupuncture by qualified practitioners 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.

The FDA has announced that “**acupuncture needles have been reclassified from Class III to Class II for ‘general acupuncture use’ by licensed, registered or certified practitioners,**” and the FDA has determined that “**the current ‘investigational use’ labeling requirements no longer apply to acupuncture needles intended for general use by qualified practitioners.**” (Acupuncture Needles Status Changed: T96-21, April 1, 1996, <http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html>). In the product Classification Database for needle, there are no special regulations for acupuncture needles (see Appendixes 8-3). The Dong Bang Acupuncture Needles Co., DBC indicates clearly, according to request 21 CFR 807.87(d), on the labeling:

“Caution: Federal law restricts this device to sale by or on the order of qualified practitioners as determined by the States”

In conclusion, in aspect of performance of sale and treatment, the DBC, Dong Bang acupuncture needles have the same intended use for the general practice of acupuncture as the legally marketed DBC (K963300) or HaengLim SeoWeon (K961677) brand acupuncture needles, and they have the same technological characteristics, as the DBC or HaengLim SeoWeon brand devices.

3. STATEMENT OF INDICATIONS FOR USE

Dong Bang Acupuncture Needles Co., DBC shows the indications (Warning, Precautions and Maintaining Device Effectiveness) for use according to the “Medical Device Labeling Suggested Format and Content Draft” issued by FDA on April 25, 1997 as follows:

Caution 1. Single use only

2. Keep away from high temperatures and humidity

3. Do not use if inside package is damaged.

Discard any unused needles in the (open) package after treatment session is complete.

With regard to “indications for use,” DBC, Dong Bang acupuncture needle labeling, the subject of this 510(K) application has the same intended use and has the same technological characteristics as the legally marketed the DBC (K963300) or HaengLim SeoWeon (K961677) acupuncture needles.

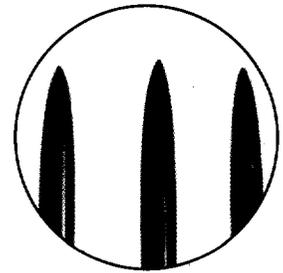
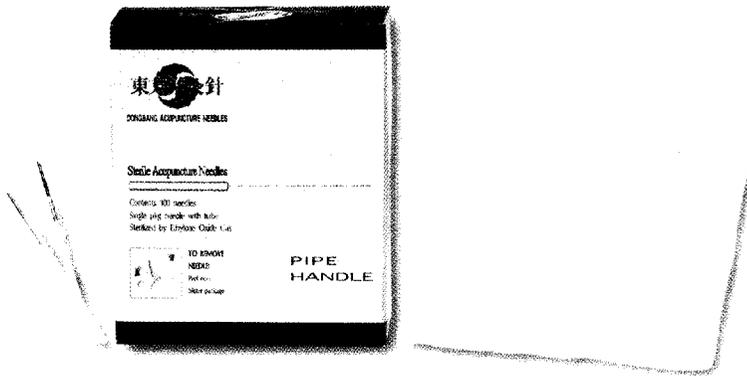
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4. PROPOSED LABELS AND LABELING

4-1 Samples of the DBC, Dong Bang Product to be Marketed

4-1-1 The Various Types of the DBC, Dong Bang Acupuncture Needle: How Supplied (Sterility, Disposable, Number and Quantity in Package)

Characteristic of DBC Needle



- the pine leaf shaped needle point
- 18-8 surgical stainless steel needle
- non-toxic, non-pyrogenic
- painless, uniform, smooth insertion
- spring & pipe handle (1.2 × 20mm)
- sterile velocity 3 years
- for electroacupuncture & moxibustion

● DBC1-1

Pipe 1' s Blister Needle; Box of 100 Needles

1 Needle With Plastic Insertion Tube Per Each Sterile (EOG) Sealed Blister Package



● DBC1-2

Spring 10's Bulk Needle; Box of 100 Needles

10 Needle With Plastic Insertion Tube Per Each Sterile (γ-ray) Sealed Bulk Package



● DBC1-3

Pipe 5' s Bulk Needle; Box of 100 Needles

5 Needle With Plastic Insertion Tube Per Each Sterile (γ-ray) Sealed Blister Package

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4-2 Samples of the Predicate Products



H.L. SEO WEON
ACU NEEDLE

HIGH QUALITY STAINLESS STEEL COIL HANDLE
STERILIZED PACKAGE DISCARD AFTER USE

LICENSE NO. 372.

1,000PCS

Pre-sterilized Gamma-Ray

DISPOSABLE ACUPUNCTURE NEEDLE

Sub Agency
HAENGLIM SEO WEON
151-5, Chunuidong, Bujcheon, Kyoungkido, Korea.
FACTORY: (032)657-5421~2
SHOP: (02) 279-1980, 275-8750
(032)657-5420

MADE IN KOREA

Size: 0.25 x 40mm
Lot No:

CAUTION
1. Single use only
2. Keep away from high temperatures and humidity
3. Do not use if inside package is damaged

Sterile Acupuncture Needles

HANDLE

DBC

DISPOSABLE ACUPUNCTURE NEEDLE

* Content is pre-sterilized by Gamma-Ray
in transparent thermo-sealed package
* Sterility guaranteed discard after use.
* Not guaranteed if reused or re-sterilized.
* High quality Stainless Steel Coil handle suitable
for moxa and electro-acupuncture.
* Please Store in a hygienic dry Place at normal
temperature.

DISPOSABLE ACUPUNCTURE NEEDLE

(DBC Brand: Made in Korea)
510(k): K963300

4-3 Description

As shown in the samples, the label and labeling of DBC, Dong Bang consists in package label, instructions for use, package inserts, prompts: size, expiration date, sterility, types, guidance for distributor. The subject of this 510(k) is guided by "Medical Device Labeling Suggested by Format and Content issued on April 25, 1997." The DBC, Dong Bang acupuncture needle has the same intended use as the DBC (K963300) or HaengLim SeoWeon (K961677) devices, and it has the same technological characteristics as the DBC or HaengLim SeoWeon brand acupuncture needles.

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5. ADVERTISEMENT FOR DONG BANG, DBC PRODUCTS

As shown by catalog (see Appendixes 8-4), the magazine (see Appendixes 8-5), and Internet Home Page (<http://www.DongBangC.co.kr>), Dong Bang Acupuncture Needles Co., DBC has activated the commercial advertisements.

Company Information



Since November 24, 1987 with permission No.263 from government, our company has been established to produce disposable needles for medical treatment in traditional oriental hospitals.

With automatical production line, we invented the needle of high technique to reduce the pain of patients with special know-how, which is the first trial in Korea. And with ability to produce 8,000,000 pieces for domestic markets such as Kyunghee Medical Center, Wonkwang Univ. Hospital.

And also we are planning to export some products, though it is small quantity, through local branches to foreign markets such as America.

Company History

- 1987. 06 Established Dong Bang Acupuncture, Inc.
- 1987. 11 Permission on manufacturing and treatment of medical instruments from Government (Ministry of Health No.263)
- 1991. 03 Established local branch in China
- 1997. 04 Q mark for guaranteeing the quality
- 1998. 04 Established local branch in the U.S.A.

Employees

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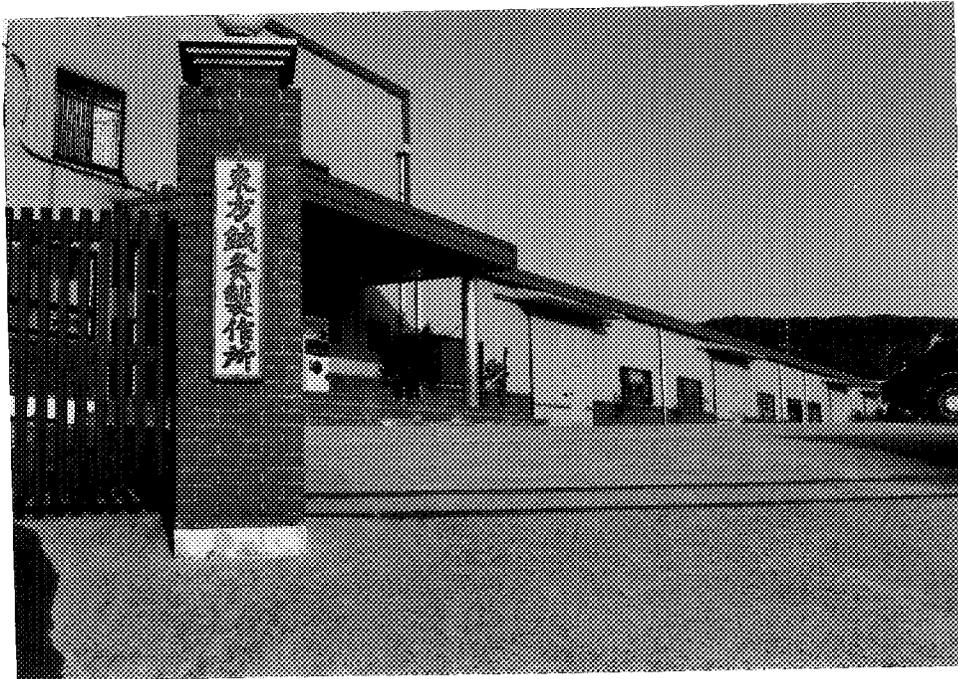
Countries Exported To

America, England, Spain, EU

Regional Offices

MorningStar. DongBang Acupuncture U.S.A., Inc.
 (staff in charge: Ae-Hoe, Kwon)
 1429 Lyndon St.
 S. Pasadena, CA 91030
 E-mail; DBCacup@aol.com
 Tel ; 626-403-5959
 Fax ; 626-403-0128

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5-2 Technology, Certification and Products of the DBC, Dong Bang

Technology

Kinds	Items with permission	No.	The concerned authority	Date
Guarantee for quality	Stainless acupuncture needle	95-057	Korean Life Goods Test Research Institute	1997. 04. 23
Utility Design	Magnetic needle	071693	The Office of Patent Administration (OPA)	1995. 03. 30
Design Registration	Magnetic needle	071398	The Office of Patent Administration (OPA)	1995. 11. 10
Design Registration	Magnetic seal	071397	The Office of Patent Administration (OPA)	1995. 11. 10
Trademark Registration	D B C	297639	The Office of Patent Administration (OPA)	1994. 09. 03

Certifications



Products

- * Acupuncture needle:
 Disposable needle (named Blister: single)
 Spring and Pipe needle (sold by bulk),
 Long needle (Gold handle needle),
 Acupuncture needle for palm and many kinds
- * Moxa
 Indirect moxa, mini moxa, pipe-shaped moxa, moxa plate, etc.
- * Suction Instrument
- * Human body shape / the picture of blood fixed places

5-3 Catalog for Sales Advertisement of DBC, Dong Bang Products:

* See Appendixes 8-4

5-3 Internet Home Page: <http://www.DongBangC.co.kr>

* See Appendixes 8-5, 19-4 ~ 10.

5-4 Dong Bang Acupuncture Needles Co. Introduced by "Giuep Nara" magazine of "The Small and Medium Industry Promotion Corporation": History, process of manufacturing, and the future prospect of DBC (see Appendixes 8-5).

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6. INFORMATION KNOWN ABOUT DEVICE'S SAFETY AND EFFECTIVENESS

Since 1988, **Dong Bang Acupuncture Needle Co., DBC of Korea** (Registration No: **8040810**) has exported Acupuncture needles to the U.S.A. through **Dong Bang USA** {a previous agent designated by DBC: 562-407-7433: 510(k) K972659}, **Lhasa Medical, Inc.** (781-335-6484: 510(k) number for the DBC acupuncture needle: **K963300**) (see **Appendixes 8-2**), **Spring Trade Co.** (213-936-5148), and **US Deer & Antler Importer and Exporter** (323-735-9665 by OEM).

At this time, no accident or device failure claims have been reported as a result of using the DBC, Dong Bang acupuncture needles of Korea. For safety and effectiveness, Dong Bang Acupuncture Needles Co., DBC has a "Q"(qualified) mark by which Korea government guarantees needle quality, and has 4 technological patent rights by the Office of Patent Administration (OPA) of Korea (see Internet Home Page, <http://www.DongBangC.co.kr> of Dong Bang Acupuncture Needles Co., 3)

Also, we are not aware of any serious or life-threatening accidents involving acupuncture needles. Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles (**cited by FDA, 510(k) no K963300 Summary**). Acupuncture needles which are currently being marketed through interstate distribution offer greater safety, since they are sterile, single use only acupuncture needles {i.e., DBC 510(k) K963300; HWA-To (K963299); HUA-XIA (K962916); CW (K964529); Seirin (K962809, K970254, K970260)}.

The subject of this 510(k) application, **DBC, Dong Bang acupuncture needle** offers safety, since it is **sterile, single use only** acupuncture needle, as the legally marketed DBC (K963300) or HaengLim SeoWeon (K961677). It is made by SUS 304 stainless steel and is sterilized **γ-ray or EOG** for 48 hours (Giuep Nara, 27-8). The safe and effective Dong Bang, DBC acupuncture needle to be marketed is "the pine leaf shaped needle point, 18-8 surgical stainless steel needle, non-toxic, non-pyrogenic, painless, uniform, and smooth insertion" (Dong Bang Acupuncture Needles Inc., DBC Catalog, 3), as the legally marketed DBC or HaengLim SeoWon needles

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7. SUBSTANTIAL EQUIVALENCE COMPARISON

7-1 Table of Similarities and Differences

Similarity: o Difference: x

Division	DBC, Dong Bang	DBC	HaengLim SeoWeon	cf. (Dong Bang)
Indications for use	o	o	o	included
Target population	o	o	o	all
Design	o	o	o	fine leaf shaped
Materials	o	o	o	18-8 surgical stainless steel
Bio-compatibility	o	o	o	indifference
Chemical safety	o	o	o	non-toxic
Compatibility	o	o	o	good
Energy used and/or delivered	o	o	o	none: safe
Human factors	o	o	o	stimulated by needle
Mechanical safety	o	o	o	safe
Performance	o	o	o	qualified practitioner
radiation safety	o	o	o	safe
Standards met	o	o	o	disposable use only
Sterility	o	o	o	Sterile (γ -ray or EOG for Dong Bang)
Where used	o	o	o	Acup. Clinic
Thermal safety	o	o	o	non- pyrogenic
Manufacture and Brand name	DBC, Dong Bang Acupuncture Needles Co.	DBC	HaengLim SeoWeon	different Brand name

7-2 Discussion of Similarities and Differences

DBC, Dong Bang method for sterilization is by γ -ray or EOG. This method is more scientifically advanced than previous methods which have been used prior to May 28, 1976. The DBC, Dong Bang acupuncture needle is similar to the predicate devices, the legally marketed DBC (K963300) or HaengLim SeoWeon (K961677) brand needles in 17 among the above 18 elements of comparison. The sole difference is in labeling. The DBC, Dong Bang acupuncture needle mentions its manufacture and brand name on label, different from the DBC brand needle.

In conclusion, the subject of this 510(k) application has the same intended use and have the same technological characteristics as the legally marketed DBC or the Haenglim Seowon acupuncture needles.

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8. APPENDIXES

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8-2	510 (k) No (K963300) submitted by Lhasa Medical Inc. for DBC brand needles exported by the same manufacture Dong Bang Acupuncture Needles Co., DBC.....	16
8-3	The Product Classification Database for Needle, Acupuncture	17
8-4	Dong Bang Acu. Needles Co., DBC Catalog	18
8-5	Advertisement for DBC, Dong Bang through Magazines	19
8-6	DBC, Dong Bang Acu. Needles Big Boxes (1000/ea) and Needles	#

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Appendix 8-1: The Letter of Authorization

Dong Bang Acupuncture Needles Co.
3-3 Kuryong Ri Ungcheon Eup
Boryeong City, Chungnam 355-850, S.Korea
Tel: (0452)33-7785, (02)518-8901(Seoul), Fax:(0452)34-5715

July 14, 1998

FDA/CDRH
HFZ-308, Device Registration & Listing (Fax: 1-301-495-4660)
Information Processing and Office Automation Branch (HFZ-308)
2098 Gaither Road
Rockville, Maryland 20850

The Letter of Authorization

Morning Star, Dong Bang Acupuncture U.S.A., Inc. is the sole domestic U. S. distributor of **the various types of sterile acupuncture needle**, and Morning Star...Inc. is authorized to list on behalf of **Dong Bang Acupuncture Needles Co.** and to maintain DBC historical listing file.

Morning Star, Dong Bang Acupuncture U.S.A., Inc. as a designated Agent of DBC is as follows:

1. **President: Ae-Hoe Kwon**
2. **Address: 1758 Foothill St. D**
S. Pasadena, CA 91030-2231
Tel: 626)403-5959, Fax: 626)404-0128, E-mail: KwonAH@aol.com
3. **FDA Registration Form, Owner/Operator No.:9034129**
4. **EIN:95-4678848**
5. **Seller's permit:** [REDACTED]

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Keun Sik Kim
President

Handwritten Korean text: 동방아침침구주식회사



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Releasable 510(k) Details

**Appendix 8-2: 510 (k) No (K963300) Submitted by Lhasa Medical, Inc.
for DBC, Dong Bang Acupuncture Needles**

U.S. Food and Drug Administration

DETAILED INFORMATION

Device Classification Name: NEEDLE, ACUPUNCTURE, SINGLE USE

510(k) Number: K963300

Device Name: DBC ACUPUNCTURE NEEDLES(SEVERAL TYPES ARE DESCRIBE

Applicant: LHASA MEDICAL, INC.

234 LIBBEY PARKWAY

WEYMOUTH, MA 02189

Contact: THOMAS RIIHIMAKI

Product Code: MQX

Date Received: 08/21/96

Decision Date: 09/23/96

Decision: Substantially Equivalent

Classification Advisory Committee: General Hospital

Review Advisory Committee: General Hospital

Statement/Summary/Purged Indicator: Summary only

Summary/Approval Letter: SUMMARY

Type: Traditional

[RETURN TO SEARCH](#)

[CDRH HOME PAGE](#)

[FDA HOME PAGE](#)

[SEND COMMENTS](#)

(Database Updated January 5, 1999)

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**Appendix 8-3: The Product Classification Database
for Needle, Acupuncture**

SEARCH RESULTS

37 records were found in the Product Classification Database for Device: *needle*
1 2 3 4

De Lente

#	Device Name	Regulation Number
1	<u>NEEDLE, CONDUCTION, ANESTHETIC (W/WO INTRODUCER)</u>	868.5150
2	<u>NEEDLE, EMERGENCY AIRWAY</u>	868.5090
3	<u>NEEDLE, ACUPUNCTURE</u>	
4	<u>NEEDLE, BIOPSY, CARDIOVASCULAR</u>	878.4800
5	<u>NEEDLE, DENTAL</u>	872.4730
6	<u>NEEDLE, ENDOSCOPIC</u>	876.1500
7	<u>SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY</u>	876.1075
8	<u>NEEDLE, PNEUMOPERITONEUM, SPRING LOADED</u>	876.1500
9	<u>NEEDLE, PNEUMOPERITONEUM, SIMPLE</u>	876.1500
10	<u>HOLDER, NEEDLE</u>	876.4730

[Return For Another Search]



(Database Updated May 5, 1998)

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DONG BANG DONG

Appendix 8-4: Dong Bang Acu. Needles Co.,
DBC Catalog

DBC[®]
DONG BANG
DISPOSABLE
ACUPUNCTURE NEEDLES

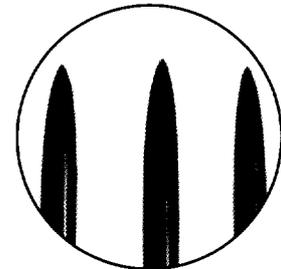


1225

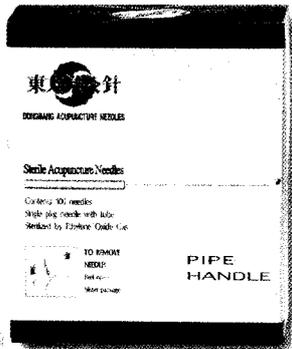
ACUPUNCTURE NEEDLES

Quality for your peace of mind painless for your patient's

Characteristic of DBC Needle



- the pine leaf shaped needle point
- 18-8 surgical stainless steel needle
- non-toxic, non-pyrogenic
- painless, uniform, smooth insertion
- spring & pipe handle (1.2×20mm)
- sterile velocity 3 years
- for electroacupuncture & moxibustion



● DBC1-1

Pipe 1's Blister Needle; Box of 100 Needles
1 Needle With Plastic Insertion Tube Per Each Sterile (EOG) Sealed Blister Package



● DBC1-2

Spring 10's Bulk Needle; Box of 100 Needles
10 Needle With Plastic Insertion Tube Per Each Sterile (γ-ray) Sealed Bulk Package

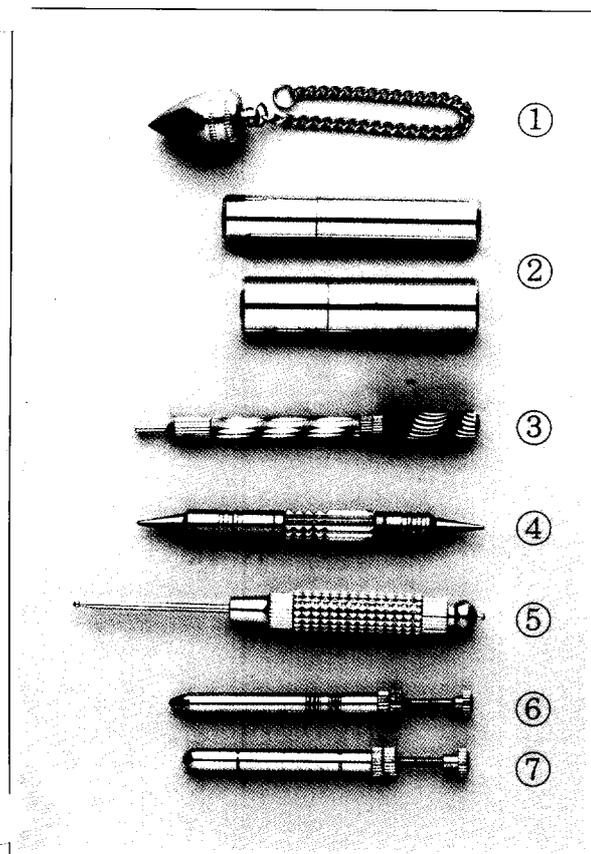


● DBC1-3

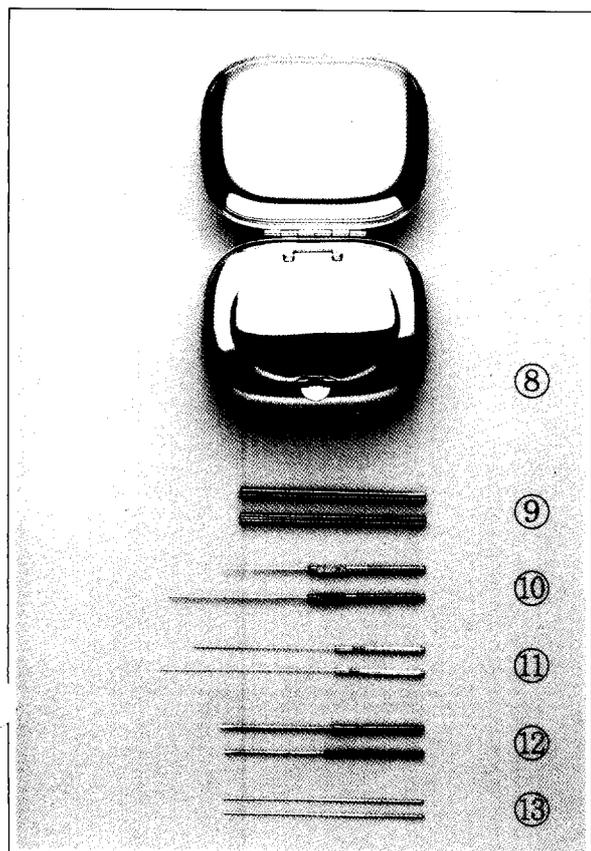
Pipe 5's Bulk Needle; Box of 100 Needles
5 Needle With Plastic Insertion Tube Per Each Sterile (γ-ray) Sealed Blister Package

Blade Diameter			Blade Length						
Korea Japanese	Chinese	(mm)	15mm (1分)	30mm (1寸)	40mm (1寸3分)	50mm (1寸6分)	60mm (2寸)	75mm (2寸5分)	90mm (3寸)
#2	#38	0.18	⊙	⊙	⊙	⊙	⊙		
#3	#36	0.20	⊙	⊙	⊙	⊙	⊙		
#5	#32	0.25	⊙	⊙	⊙	⊙	⊙		
#8	#30	0.30	⊙	⊙	⊙	⊙	⊙	⊙	⊙
#10	#28	0.35	⊙	⊙	⊙	⊙	⊙	⊙	⊙

ASSORTED NEEDLES



- DBC5-1 Oscillator
- DBC5-2 Shumo Needle (皮膚鍼)
- DBC5-3 Finger Needle Injector (手指鍼管)
- DBC5-4 Duo-Probe Rolling Needle (壓迫鍼)
- DBC5-5 Tei-Shin Spring Modulator (無痛鍼)
- DBC5-6 Spring Needle for Baby (自動小兒鍼)
- DBC5-7 Spring Tie-Edged Needle (自動三稜鍼)



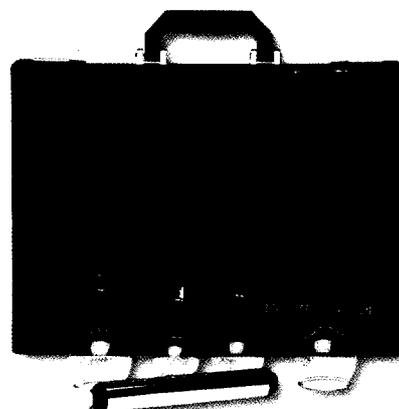
- DBC5-8 Cotton Case (消毒器)
- DBC5-9 Needle Tube (鍼管); Stainless / P.V.C
- DBC5-10 4-Punched Needle (四孔鍼)
- DBC5-11 Golden Handle Needle / White Handle Needle (黃頭鍼 / 白頭鍼)
- DBC5-12 Triple-Edged Needle (三稜鍼)
- DBC5-13 Han Needle (韓鍼); A, B

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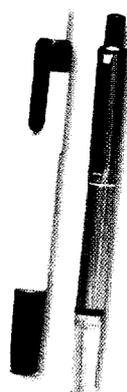
MOXA & LANCET



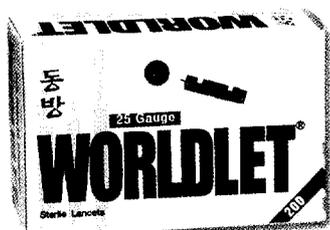
● **DBC3-1**
Plastic Suction Set; A Set With 15 Cups



● **DBC3-2**
Glass Suction Set; A Set With 14 Cups



● **DBC4-1**
Auto-Lancet Injector; Stainless / P.V.C



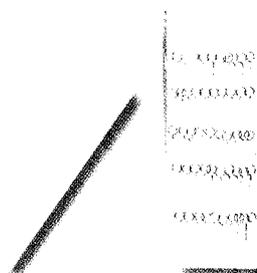
● **DBC4-2**
Lancet Needles; A Box of 200 needles;
#21 (0.8mm), #23 (0.60mm), #26 (0.45mm)



DBC® 東方鍼灸鍼



● **DBC1-4**
Press Tack Needle (耳鍼);
Box of 50 Needles Each With Tape



● **DBC1-5**
Intradermal Needle (皮内鍼);
Bulk of 50 Needles



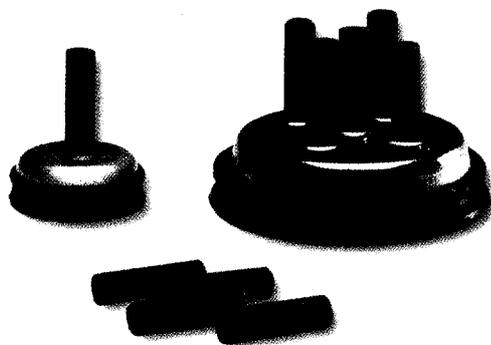
● **DBC2-1**
Gold Moxa (Super & Ultra Pure);
Bulk of 7.5 Grams



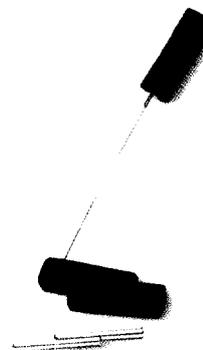
● **DBC2-2**
Pungnyon Moxa (Stick on Moxa);
Box of 225 Pcs



● **DBC2-3**
Arirang Moxa (Stick on Moxa);
Box of 200 Pcs



● **DBC2-4**
KU-Pun Burning Bowls; Five Hole Bowls,
One Hole Bowls
KU-Pun Moxa; 200 per Package



● **DBC2-5**
Needle Moxa (Smokless); Box of 200 Moxa
Metal Caps; 100 per Package

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 **DONG BANG ACUPUNTURE, INC.**

DBC 東方鍼灸製作所

Office: #403 Yongjin B/D, 10-37, Jamwon-dong,
Seocho-gu, Seoul 135-030

Tel: (82-2)518-8901 Fax: (82-2)518-9477

Factory: 3-3, Kuryong-ri, Ungcheun-eup,

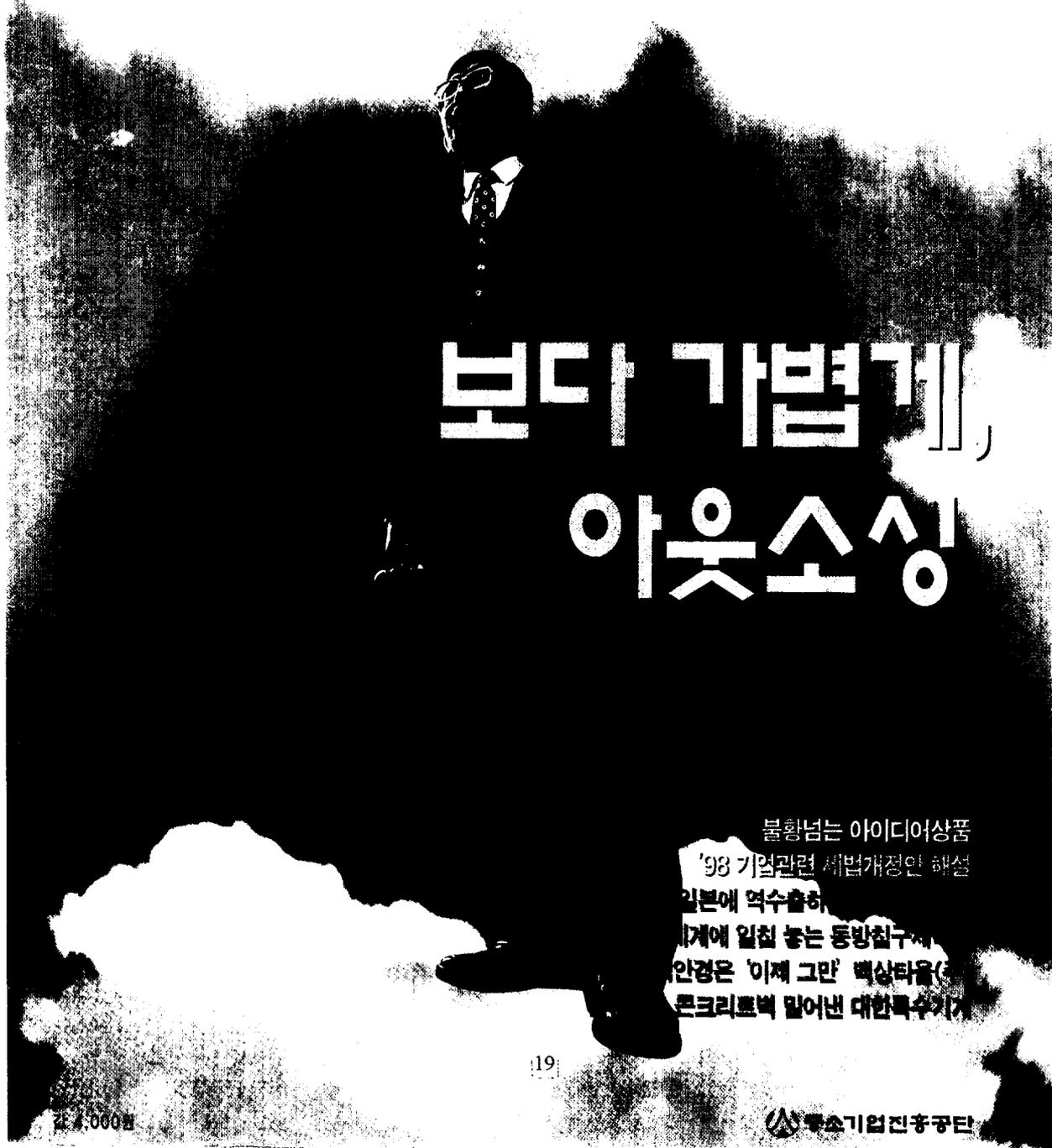
Boryeong-city, Chungnam 355-850

Tel: (82-452)33-7785 Fax: (82-452)34-5715

Appendixes 8-5: Advertisement for DBC, Dong Bang through Magazines

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Direk



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우리 침으로 세계에 '일침'

침(鍼) 제조업체 국내 선두 ... 세계를 무대로

글 / 구규욱



한방치료법이라면 흔히 침술치료와 뜸요법인 침구요법(鍼灸療法)을 말한다. 이 한방치료법이 최근 들어 세계적으로 관심이 높아지면서 부쩍 침구에 관한 연구가 가속화되고 있다. 그 중에서도 특히 침술(鍼術)에 대해 서양에서는 '동양 신비의 의학'이라 부르며 치료의학으로서 가치와 효능을 인정

하는 등 새로운 연구분야로 자리잡고 있다. 침술의 효능은 이미 미국 의학계에서도 입증돼 있을 정도다. 우리나라엔 이미 많은 대학에 한의대가 설립돼 있으며, 국내 한의사들도 매년 미국, 일본 등 해외에서 동양의학세미나를 개최하는 등 '한방의 세계화'를 위해 뛰고 있다.

우리 나라의 일부 대학에서는 지금 의학 종합연구소 설립을 추진하면서 한방치료를 양방치료를 겸하는 동서의학 종합병원을 계획하고 있어 한방(韓方)과 양방(洋方)이 협조·병행 치료하는 종합병원의 출현이 기대되고 있다. 이제는 의학계에서도 예전과 같이 민간요법으로 취급하려는 인식이 없어졌고, 한의학계에서도 본격적인 의학으로서 '한방의 과학화'를 추진하고 있는 추세다.

한편, 침술요법(鍼術療法)은 일반인들 사이에서도 가정의학이나 응급처치용으로 숙지하고 있을 정도로 활성화되어 있다. 특히 올림픽 등 세계 규모의 각종 스포츠대회가 열릴 때면 동양의 침술요법이 크고 작은 부상치료에 그 효과를 유감없이 발휘하고 있으며, 그럴 때면 의

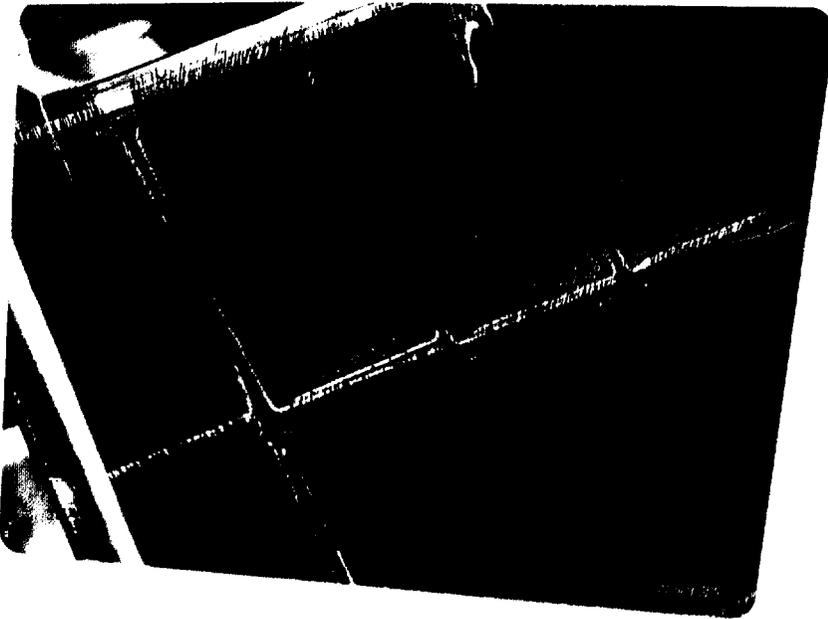
국인들은 어떻게 그 작은 침(鍼) 하나로 순간적인 치료가 가능한지, 또 사람 몸의 경혈(經穴)과 건강은 어떤 연관이 있는지의 아함을 느낀다고 한다.

서양의학이 외상의 부상 부위를 직접 치료하는 하드웨어적인 성격을 갖고 있다면 동양의학은 같은 외상이라도 통증과 관련된 되는 신체의 내부기능까지 진단해 경혈을 통해 처방하는 소프트웨어적 요법이라는 점에서 차이를 보이고 있다는 게 전문가들의 지적인데, 바로 이런 차이가 서양의학으로부터 관심을 불러일으키는 점이라 하겠다.

따라서 앞으로는 진단과 원인발견은 서양의학이, 치료·처치는 동양의학이 담당하는 요법으로 접목·발전돼야 한다고 한 의학계에서는 말하고 있다.

침(鍼) 제조 자동화 실현

이렇듯 동서양 구분없이 한의학에 대한 연구가 활발해지고 침술요법의 관심이 커지면서 당연히 수요가 증대되고 있는 게



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바로 칩(鐵). 특히 우리 교포가 해외에서 활동을 많이 하게 되면서 우리 나라 칩술도 해외에 많이 보급되었으며 앞으로도 칩의 수요는 급증할 전망이다.

세계에서 칩술요법이 발달한 나라는 중국, 일본, 우리 나라 그리고 대만을 꼽으며 칩을 제조해 공급하는 것도 바로 이 나라들이다. 그러나 아직까지 네 나라 모두 칩 제조기술은 다른 업종의 기술에 비해 상당히 뒤떨어져 있는 게 현실이다.

한방의 과학화와 세계화를 위해 국내 한의학계가 노력하고 있는 가운데, 칩술 보급과 함께 국내외에서 1회용 소모품으로 수요가 증가하고 있는 칩의 품질향상과 원가절감은 가장 중요하고 시급한 일이기도 하다.

이런 상황에서 국내 칩 제조업체의 선두주자로 인정받고 있는 회사는 충남 보령시 웅천농공단지에 있는 동방칩구제작소(東方鐵灸製作所·대표 김근식·43세).

이 업체는 자동화가 쉽지 않은 칩 제조공정을 자동화함으로써 품질향상과 원가절감을 실현하며 부가가치를 높이기 위해 힘쓰고 있다. 자동화가 가능한 공정이라 해도 경제성이 없다면 자동화의 가치가 없는데 이 회사는 자동화를 통해 효과를 거두고 있는 것이다.

칩은 대략 12개의 제조공정을 거친다. 스테인리스 강선(SUS 304)을 원자재로 쓰는 칩은 원자재가공(칩병(손잡이)·파이프, 스프링), 칩체가공(굴곡 절단), 칩병과 칩체조립(심기), 고정(뿔기), 절단, 칩첨연마, 검사, 세척, 포장 및 무균 보존을 위한 48시간 γ-Ray 멸균소독 등의 공정을 거치게 되는데, 7개업체로 추산되는 국내 영세 제조업체들은 거의 모든 공정을 반자동과 수동에 의존하고 있어 낮은 부가가치로 고전하고 있

는 형편이다.

그러나 동방의 경우는 다르다.

중소기업진흥공단 자동화지도팀의 지도와 자체 노력으로 기계가공과 칩체가공, 조립의 일부공정을 자동화해 품질균일화와 인력절감을 이룬데 이어 칩 제조공정 중 가장 중요한 절연연마공정을 완전자동화함으로써 국내 칩 중 최고의 품질을 자랑하고 있는 것이다.

“우리가 흔히 한의원에서 접하는 칩은 보기와는 달리 까다로운 점이 많습니다. 칩에서 가장 중요한 곳이 칩침(鐵針)이죠. 경혈을 아프지 않게 찔러줄 수 있어야 합니다. 칩 맛을 내고 통이 심하면 곤란한 일이 많아요? 아주 옛날에는 돌을 가늘게 갈은 석침(石鍼)을 썼다고 합니다. 그 다음에는 철침(鐵鍼)이었는데 그 때만 해도 칩 맛을 때 얼마나 아팠습니까? 칩의 끝부분이 좋아야 환자에게 고통을 주지 않을 수 있습니다.”



이직은 생각보다 시장이 넓지 않고 부가가치 또한 그리 높은 편이 아니기 때문에 자동화를 통한 품질향상으로 승부할 수밖에 없다고 김사장은 말한다. 동방은 현재 제조공정의 60% 정도를 자동화하는데 성공했으며, 심기(조립)공정과 뿔기(고정)공정을 완전자동화하기 위한 기술적인 검토도 끝났다.

칩은 수지칩(7mm)과 호침(30~40mm), 장침(150~300mm)으로 나뉘는데 동방에서는 지금 호침을 주로 만든다. 동방이 생산하는 칩은 대형 한방종합병원에 직접 납품하고 있으며 의료가 판매업자나 대리점을 통해 판매되는 등 전국의 40% 정도를 동방이 공급하고 있다.

동방의 제품은 일본에서도 호평을 받고 있어 작년에 약 10만 불 정도의 수출을 기록했다. 품질차별화가 쉽지 않은 제품의 특



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성상 침을 수출하기란 그리 쉽지만은 않지만 해외판로를 개척한 동방은 계속해서 교포들이 많이 살고 있는 미국시장을 공략하기 위해 노력하고 있다. 또한 김사장은 침구학회에서 실시하는 한방의료봉사에 매번 참석하며 지원을 아끼지 않고 있다.



중국보다 싸게, 일본보다 질 좋게

김사장이 침구 제작을 시작한 것은 지난 82년, 경희대학교 원예과를 졸업하고 학교에 근무하던 그는 우연히 친한 교수의 권유로 경기도 의왕에서 1회용 호침을 생산하기 시작했다. 한방과 침구에 대해 전혀 문외한이었으나 한의학과 교수들과 한의사들로부터 침에 대해 배워가며 수작업으로 만들어갔다. 어느 정도 경험을 쌓은 그는 87년에 보건사회부의 의료기제조업 허가를 받고 88년부터 모교인 경희대학을 비롯한 한방병원에 납품하기 시작하면서 사업다운 사업을 해 나갔다. 인체와 경혈의 관계, 침구의 중요성 등을 깨우치면서 본격적으로 사업을 하기 위해 94년에는 무창포 해수욕장이 가까운 용천의 농공단지에 대지 1,500평, 건평 720평 규모의 자가공장을 마련, 입주한다. 그러나 이 무렵, 침 제조가 다른 사업에 비해 비교적 손쉬웠는지 경쟁업체들이 출현하면서 가격경쟁은 시작됐고 중국에서 들어오는 저가제품으로 인해 한동안 시달렸는데 이 때가 가장 힘들었다고 회상한다.

그러나 기술과 품질로 승부하겠다는 김사장의 집념은 자동화를 위한 노력으로 이어져 지금은 국내업체는 물론 중국을 비롯한 경쟁업체들보다 생산성과 품질면에서 우위를 지키고 있다며 자신감을 갖는다.

"현재 침을 만드는 회사는 중국에 10개 정도, 일본과 우리나라가 7개씩, 대만에 4개 정도가 있는데 시장규모가 큰 미국시장에는 아직까지 중국제품이 가장 많이 들어가고 있습니다. 그러나 제가 알기로는 자동화율 60% 정도의 업체는 찾아보기 힘들 정도고, 앞으로 계획하고 있는 조립과 고정, 절단공정만 자동화한다면 완전자동화가 되면서 품질이나 가격경쟁에서 우리가 충분히 이길 수 있을 것으로 확신합니다."

김사장의 노력은 이것으로 끝나지 않는다. 자기장을 이용해 침치료 효과를 극대화하기 위한 자기침(磁氣鍼)을 개발, 지난 7월말에 특허를 획득했으며 상품화에도 성공했다. 또한 속의 온혈, 정혈, 항균, 원기회복과 저항력 강화 등의 효능은 미국 FDA에서도 인정하고 있는데, 지금 생산해 판매하고 있는 속뜸



충남 보령시 용천농공단지에 자리잡고 있는 동방침구제작소 전경(위), 김근식 사장(아래).

기에 마늘과 한약재를 혼합 가공해 치료효과를 높이기 위한 신제품도 개발해놓은 상태다.

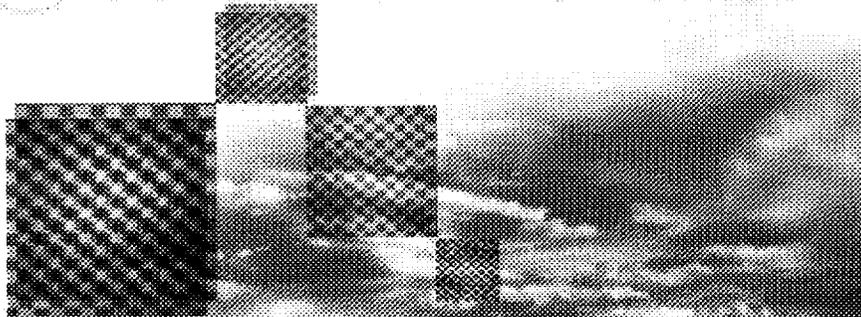
문의한에서 시작해 인체의 원리와 한방건강에 대해 거의 전문가가 된 김사장은 최고의 국난이라 부르는 IMF 극복에 대해 다음과 같이 말하며 끝을 맺는다.

"모든 것은 자기자신에게 달려 있다고 생각합니다. 자기가 가장 중요합니다. 정부나 지원기관은 정말로 자생력 있는 기업을 선정해 지원해줘야 하고, 기업은 싸고 좋은 제품을 만들기 위해 피땀을 흘려야 한다고 생각합니다. 제 목표는 한 가지뿐입니다. '중국제품보다 싸게, 일본제품보다 좋게' 만들어, 이제 서구에서도 의학으로 인정받고 있는 침술에 우리 침을 쓸 수 있도록 할 겁니다. 이것만큼은 꼭 이룰 겁니다." ●

기업연구 · 동방침구제작소

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DBC DONG BANG ACUPUNCTURE, INC.



Welcome to our Company



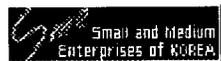
Company Information
Information for the President



Message from technology Business Product Register Bulletin
Information Line Information Board

Korean

E-mail



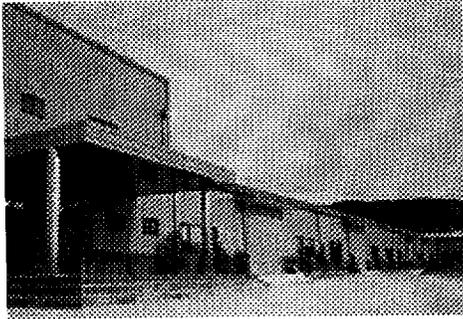
19-4 Internet Home Page:
[Http://www.DongBangC.co.kr](http://www.DongBangC.co.kr)

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DONG BANG ACUPUNCTURE.,INC. : Proverbial DBC...

Company Information

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Since November 24, 1987 with permission No.263 from government, our company has been established to produce disposable needles for medical treatment in traditional oriental hospitals.

With automatical production line, we invented the needle of high technique to reduce the pain of patients with special know-how, which is the first trial in Korea. And with ability to produce 8,000,000 pieces for domestic markets such as Kyunghee Medical Center, Wonkwang Univ. Hospital.

And also we are planning to export some products, though it is small quantity, through local branches to foreign markets such as America.

Company History

- 1987. 06 Established Dong Bang Acupuncture.,Inc.
- 1987. 11 Permission on manufacturing and treatment of medical instruments from Government (Ministry of Health No.263)
- 1991. 03 Established local branch in China
- 1997. 04 Q mark for guaranteeing the quality
- 1998. 04 Established local branch in the U.S.A.

Employees

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Countries Exported To

America, England, Spain, EU

Regional Offices

MorningStar. DongBang Acupuncture U.S.A., Inc.
 (staff in charge: Ae-Hoe, Kwon)
 1429 Lyndon St.
 S. Pasadena, CA 91030
 E-mail; DBCacup@aol.com
 Tel ; 626-403-5959
 Fax ; 626-403-0128



* Homepage : <http://www.dongbangc.co.kr>

* Company : DONG BANG ACUPUNCTURE.,INC.

* Phone : (1) 82-452-933-7785
 (2) 82-2-518-8901

* FAX : (1) 82-452-934-5715
 (2) 82-2-518-9477

* Address : (1) 3-3,KURYONG-RI,UNGCHON-EUP,PORYONG-SHI,CHUNGNAM,KOREA (ZIP :355-850)
 (2) RM403,YONGJIN B/D,10-37,CHARMWON-DONG,SEOCHO-GU,SEOUL,KOREA (ZIP :137-030)

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Message from the President

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In 1987 with strong will to make the cheapest and comfortable medical instrument, we, Dong Bang Acupuncture succeeded in manufacturing the acupuncture needles automatically for the first time in Korea.

We acquired the first Utility Design Patent on Automatic Needle Grinder in Korea. Therefore we can be the international company in manufacturing the acupuncture needle with the large facility of automation line (size: 2,376 μ s³). As well, we recognized the difficulties in export such as globalization, price competition, overcoming the barriers in trade, and the expansion of world market. So we established local office in China in 1992, and in the U.S.A. in 1998.

We also make other medical instruments like moxa and completed 80% of automation line production. Furthermore, we accomplished over 40% sales in domestic markets as a leading company. With 10 years experience of sale, we have provided these good products to over 80% of oriental medical hospital like Kyunghee Medical Center, Wonkwang University Hospital, etc.

We do our best to multiply the items and research the products for survival in hot domestic acupuncture production competition, while we also try to expand the overseas markets to the U.S.A., China and Europe with the complete 100% automatic production line.

Like this, our technique is best of all in the world and is now known internationally thanks to globalization of acupuncture treatment. Now we confirm our place as a leading company of manufacturing acupuncture products in the world.



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Technology

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Kinds	Items with permission	No.	The concerned authority	Date
Guarantee for quality	Stainless acupuncture needle	95-057	Korean Life Goods Test Research Institute	1997. 04. 23
Utility Design	Magnetic needle	071693	The Office of Patent Administration (OPA)	1995. 03. 30
Design Registration	Magnetic needle	071398	The Office of Patent Administration (OPA)	1995. 11. 10
Design Registration	Magnetic seal	071397	The Office of Patent Administration (OPA)	1995. 11. 10
Trademark Registration	D B C	297639	The Office of Patent Administration (OPA)	1994. 09. 03

Certifications



Products

- * Acupuncture needle:
 Disposable needle (named Blister: single)
 Spring and Pipe needle (sold by bulk),
 Long needle (Gold handle needle),
 Acupuncture needle for palm and many kinds
- * Moxa
 Indirect moxa, mini moxa, pipe-shaped moxa, moxa plate, etc.
- * Suction Instrument
- * Human body shape / the picture of blood fixed places



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The amount of needle production : 8,000,000 pieces a month

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The amount of moxa production : 20,000 boxes a month



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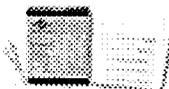
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DISPOSABLE ACUPUNCTURE NEEDLE



1. The end part (the point of needle) is grinded as the shape of pine tree leaf to reduce the pain when it is treated on the body.
2. The handle part of needle has comfortable shapes with pipe and spring to be used easily.
3. Various kinds of packing and products are devised according to production of the small quantity of multi-items.

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MOXA



1. Mixed with traditional treatment in Orient and comfortable way to use, this can be used easily at home.
2. Ordinary people as well as doctor can use it.



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Bulletin Board

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	Poster	Date	No. of Search	Subject
2	Ae-Hoe Kwon	1999-01-23	2	Waiting for OBL and Parcel, congratulati...
1	Ae-Hoe Kwon	1999-01-23	1	Waiting for OBL and Parcel, congratulati...



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