K052731

FEB 1 2006

510(k) Summary

1. **Submitter's Identification:**

Lee & Xiao
2600 Mission Street, Suite 100
San Marino, CA 91108
Tel: (626)799-0998
Fax: (626)799-1588

Contact Person: Yingchao Xiao, Esq

Date: September 27, 2005

2. **Device Name:**

Trade Name:	Kangsheng Brand/Kangnian Brand/Unilink Brand/ Huazhong Brand Acupuncture Needles
Common Name:	Acupuncture Needle
Classification Name:	Needle, Acupuncture, Single Use

3. **Predicate Device Information:**

Vinco Brand Acupuncture Needle (K024207)
Acumaster Band Acupuncture Needle (K991508)
Carbo Brand/Viva Brand Acupuncture Needles (K961339)

4. **Device Description:**

The Device is defined as prescription device intended to to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. The Device consists of a solid stainless steel needle with handle attached to the neelde to facilitate the delivery of acupunture treatment. The material for the needle of the Device is stainless steel wire 0Cr19Ni9, which complies with the Chinese National Standard GB2024-94 for acupuncture needles.

The handles of the Device are in flat, ring, flower or tube shape and are made of different materials including copper, stainless steel, aluminum, and plastic. The length of the Device conforms to GB2024-94, which meets the needs for depth of insertion and manipulation. The diameters of the needle come in 0.16mm, 0.18mm, 0.20mm, 0.25mm, 0.30mm, 0.35mm, 0.40mm, and 0.45mm, depending on the needs. The point of the needle is round, straight, and smooth and complies with GB2024-94.

Each acupuncture needle is individually packaged, with or without a guide (insertion) tube. The Device is sterilized with Ethylene Oxide, whose residue on the surface of needle body meets clinical health requirements. The Device package is confirmed to remain stainless and aseptic in two years of shelf life at room temperature, normal pressure, and ≤80%RH.

The Device is sterile, disposable, and for single use only. The material, sterility, and biocompatibility of the Device meet the general specifications and the criteria for single use acupuncture needle. In addition, the Device is designed such that it is compatible with the current acupuncture needles produced by other major acupuncture needle manufacturers.

5. Intended Use:

The device is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

6. Conclusion:

Kangsheng Brand, Kangnian Brand, Unilink Brand, and Huazhong Brand Acupuncture Needles are very similar to the Predicate Device in all areas of comparison. Where there is a difference in the subject device, the difference does not raise any question in terms of the subject device's safety and effectiveness. Therefore, Kangsheng Brand, Kangnian Brand, Unilink Brand, Huazhong Brand Acupuncture Needles are substantially equivalent to Vinco Brand, Acumaster Brand, Carbo Brand/Viva Brand acupuncture needles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

Mr. Daxin Li
C/O Mr. Yingchao Xiao
Lee & Xiao Attorneys
2600 Mission Street, Suite 100
San Marino, California 91108

Re: K052731
Trade/Device Name: Kangsheng Brand/Kangnian Brand/Unilink Brand/Huazhong Brand Acupuncture Needles
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: January 9, 2006
Received: January 13, 2006

Dear Mr. Xiao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). 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.

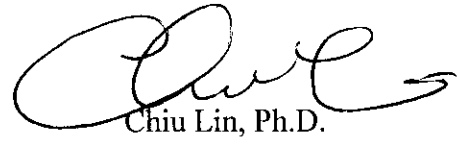
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052731

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Kangsheng Brand/Kangnian Brand/Unilink Brand/Huazhong Brand Acupuncture Needles

Indications for Use:

The device is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use ___X___	AND/OR	Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] General Hospital
[illegible] Dental Devices

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