NOV 1 3 2002

MANDALA HEALTH CARE, LLC

13740 Midway Rd., Suite 801 Dallas, Texas 75244
Phone: (972) 977-4180 Fax: (972) 404-4404

510(k) Number: K-023054

II. 510(k) Summary

As required by Section 807.92(c)

Device Name:	**Jia Chen Acupuncture Needle**
Classification Name:	**Needle, Acupuncture, Single Use**
Regulation Number:	**880-5580**
Product Code:	**MQX**
Regulatory Class:	**II**

510(k) Applicant: **Mandala Health Care, LLC**
13740 Midway Rd., Suite 801
Dallas, Texas 75244

Contact: **Dashima Dovchin, President**
Phone: (972) 977-4180
Fax: (972) 404-4404

510(k) Submitter: **Wujiang Jia Chen Acupuncture Devices Co., Ltd.**
Wujiang City, Jiangsu Province, China

Identification of predicate device(s):

Kangnian Brand Acupuncture Needle, Single Use
Manufactured by Suzhou Kangnian Medical Devices Co., Ltd.
510(k) Number: K991507

Spirit Brand Acupuncture Needle, Single Use
Manufactured by Wujiang Acupuncture Needle Factory
510(k) Number: K003010

Shen Ling Brand Acupuncture Needle, Single Use
Manufactured by Shen Ling Medical Devices Co., Ltd.
510(k) Number: K002411

Description of the Device:

The Jia Chen Acupuncture Needles are defined as prescription devices intended to pierce the skin in the practice of acupuncture as determined by the States. The device consists of a solid stainless steel needle with handle attached to the needle to facilitate the delivery of acupuncture treatment. The material for Jia Chen Acupuncture needles is Austenitic stainless steel wire of ASMTF 899-94, type 304, which holds Certificate of Quality Control Approvals issued by China Quality Certification Center for Import and Export Commodities and holds the Mill Certificate of Chemical Composition and Physical Properties of needle material.

The needle body is vacuum melted high purity stainless steel, with a good body tensile and spring, and the body surface finish has no visible defects under 100X magnifications. Jia Chen Acupuncture needle handles come in many different materials including copper, silver, plastic, steel tube and all stainless steel. The needle to handle bond strength is of at least 1 kilogram.

The each single acupuncture needle is packed in plastic guide (insertion) tube, which facilitates the delivery of needles in treatments and protects the healthcare worker's hand from accidental needle sticks.

Jia Chen Acupuncture needles are sterilized with Ethylene Oxide GB 13098-98 and device sterility level (SAL) is at least 10^{-6}. The ethylene oxide residue level in finished devices does not exceed EtO 25 ppm, Ethylene glycol 250 ppm, and ethylene chlorohydrin 25 ppm.

Jia Chen Acupuncture needles are sterile, and for single use only. The material, sterility, and the biocompatibility of these acupuncture needles meet the general specifications and the criteria for single use acupuncture needle. In addition, the Jia Chen Acupuncture needles are designed such that they are compatible with the current acupuncture needles produced by the other major acupuncture needle manufacturers.

Indications for Use:

Jia Chen Brand Acupuncture needles will be used as directed: "**Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States**".

Jia Chen Acupuncture needles are labeled, "**Sterile Acupuncture needles for single use only**" and also have a prescription statement on the box, "**Caution: Federal Law restricts this device to sell by or on the order of a qualified practitioner of acupuncture as determined by the States**".

The Food and Drug Administration has issued 510(k)'s to over 50 different single use acupuncture needle brands and they are been used for general practice of acupuncture in the United States since 1996. We have searched the Federal Consumer Information Center official website (http://www.pubeblo.gsa.gov) and the U.S. Consumer Product Safety Commission official website (http://cpsc.gov) and have found no serious life threatening accidents involving acupuncture needles.

The subjects of this 510(k) application, The Jia Chen Brand Acupuncture needles, are sterile and are for single use only. The design, material, sterility, and the biocompatibility of these acupuncture needles meet the general specifications and the

criteria for single use acupuncture needle and are effective for the practice of acupuncture.

Conclusion:

The Jia Chen Acupuncture needles have the same technological characteristics (design, material, sterility, and biocompatibility) and the same intended use as the predicate needle devices. Therefore, Jia Chen Acupuncture needles are substantially equivalent to the other acupuncture needles that are currently being marketed in interstate commerce. In conclusion, based on the information provided with this 510(k) Notification, Jia Chen Acupuncture needles meet the criteria for FDA 510(k) acceptance.

Mandala Health Care Dallas Texas USA Limited Liability Company

Dashima Dorchin, President
Mandala Health Care, LLC

10-10-02
Date Prepared

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Ms. Dashima Dovchin
President
Mandala Health Care, LLC
13740 Midway Road, Suite 801
Dallas, Texas 75244

Re: K023054
Trade/Device Name: Jia Chen Acupuncture Needle
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQA
Dated: October 21, 2002
Received: October 23, 2002

Dear Ms. Dovchin:

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.

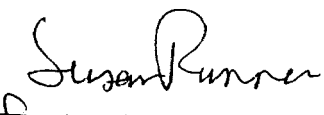
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K023054

III. Statement of Indications for Use

510(k) Number: K-023054

Device Name: **Jia Chen Acupuncture Needle**

Indications for Use:

Jia Chen Acupuncture Needle will be used for "Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023054

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 3-10-98)