5. 510(k) Summary

K090910

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See 510(k) Summary, below.

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1. Trade Name: . Hansol Acupuncture Needle
   Common Name: Single use, Acupuncture Needle.
   Classification Name: Single use, Acupuncture Needle.
   Product Code: MQX
   Regulation: 880.5580
   Class of device : ClassII.

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2. The legally marketed device to which we are claiming equivalence:
   ASIA-MED Single use, Acupuncture Needle. K052085

3. Description of device: Hansol Acupuncture Needle consists of components commonly found on Single use, Acupuncture Needle.

   The Hansol acupuncture needle is a sterile surgical stainless steel, single use only acupuncture needle. The Hansol acupuncture needle meets the general specification and criteria for an acupuncture needle and is effective for the practice of acupuncture.

4. Intended Use: An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

5. Technological Characteristics: Hansol Acupuncture Needle and the predicate device have identical technological characteristics and perform the same way as common acupuncture Needle
   They are sterilized

6. Performance: Bench tests were performed.
   Bench testing included biocompatibility, sterility testing.
   The tests demonstrated that the device is as safe , as effective and performs in a substantially equivalent manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Hansol Medical Company
C/O Mr. Peter Chun
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K090910
Trade/Device Name: Hansol Acupuncture Needle
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: June 9, 2009
Received: June 22, 2009

Dear Mr. Chun:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K090910

Device Name: **Single use, Acupuncture Needle**

Indications For Use:
An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

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)

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

510(k) Number: K090910