



Food and Drug Administration
10903 New Hampshire Avenue
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August 1, 2014

SMC
Mr. Jong-man Lee
President
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KOREA

Re: K141473
Trade/Device Name: SMC Acupuncture Needle
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture needle
Regulatory Class: II
Product Code: MQX
Dated: June 10, 2014
Received: June 12, 2014

Dear Mr. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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/MedicalDevices/Safety/ReportaProblem/default.htm> 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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141473

Device Name

SMC ACUPUNCTURE NEEDLE

Indications for Use (Describe)

SMC ACUPUNCTURE NEEDLE is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Digitally signed by Richard C.
Chapman -S

Date: 2014.08.01 11:19:39 -04'00'

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Description of the Device**807.92(a)(4)**

The Acupuncture Needles are sterile, hair thin needles which are inserted into specific points on the skin, called “acupuncture points”. The Acupuncture Needles are manufactured from stainless steel and sterilized with gamma irradiation and/or ethylene oxide.

The Acupuncture Needles are available in nine needle diameters (0.16 to 0.70 mm), ten needle lengths (15-135 mm), and ten tube lengths (30-160 mm).

Statement of the Intended Use**807.92(a)(5)**

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

Summary of the technological characteristics of the device compared to the predicate devices**807.92(a)(6)**

The SMC ACUPUNCTURE NEEDLE is substantially equivalent to WOOJEON ACUPUNCTURE NEEDLE. Table 1 summarizes the technological characteristics of the SMC ACUPUNCTURE NEEDLE vs. the predicate device.

Table 1:**Comparison of SMC ACUPUNCTURE NEEDLE and WOOJEON ACUPUNCTURE NEEDLE**

| Attribute | SMC ACUPUNCTURE NEEDLE K- | WOOJEON ACUPUNCTURE NEEDLE K111392 |
|--------------------------------|--|--|
| Indications for Use | This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. | This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. |
| Available in needle diameters | 0.16 to 0.70 mm | 0.16 to 0.50 mm |
| Available in needle lengths | 15-135 mm | 15-60 mm |
| Available in tube | 30-160 mm | 30-145 mm |
| Material (part of needle body) | 304 stainless steel | 304 stainless steel |
| Coating | Polydimethylsiloxane | Polydimethylsiloxane |

| Attribute | SMC ACUPUNCTURE NEEDLE K- | WOOJEON ACUPUNCTURE NEEDLE K111392 |
|----------------------|---|--|
| Sterilization method | Radiation (Gamma) for Pouch and/or Ethylene oxide of Blister | Radiation (Gamma) for Pouch |

Non-clinical Performance Data**807.92(b)(1)**

Performance testing was conducted to evaluate and characterize the performance of the SMC Preclinical testing conducted included dimensional conformance evaluation, visual inspections, and design verification to confirm airway passage equivalency and biocompatibility testing based on the applicable elements of ISO 10993 series.

Clinical Data**807.92(b)(2)**

Comparison with the predicate indicates they are similar in functions and efficiency, and the post market experience proves that it is substantially equivalent.

Conclusion**807.92(b)(3)**

Biocompatibility tests and performance tests show that the device meets the requirements of those standards. Literatures and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specification and performance. Thus, we conclude that WOOJEON ACUPUNCTURE NEEDLE is substantially equivalent to the predicate device.