June 10, 2015

K.M.S. Inc.
c/o Mr. Charlie Mack
International Regulatory Consulting
12226 Washington Lane
Parker, Arizona 85344

Re: K142920
   Trade/Device Name: KM Needles (Acupuncture Needle)
   Regulation Number: 21 CFR 880.5580
   Regulation Name: Acupuncture Needle
   Regulatory Class: II
   Product Code: MQX
   Dated: April 29, 2015
   Received: May 06, 2015

Dear Mr. Mack:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for 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
510(k) Number *(if known)*
K142920

Device Name
KM Needles (Acupuncture Needle)

Indications for Use *(Describe)*
This KM Needles (Acupuncture Needle) is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state regulations.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

*CONTINUE ON A SEPARATE PAGE IF NEEDED.*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 29, 2015
510(k) Number: K142920

1. Company and Correspondent making the submission:
   Name – K.M.S Inc.
   Address – F2, 81-1 Haengjeong-ri, Gwangdeok-myeon, Dongnam-gu, Cheonan-si, Chungcheongnam-do, Korea 330922
   Tel: 82-41-5587785
   Fax: 82-41-5587786
   Contact – Mr. Chul Hui.Kim
   Executive Director
   Email – charliemack@irc-us.com

2. Device:
   Trade/proprietary name: KM Needles (Acupuncture Needle)
   Common Name: Acupuncture Needle
   Classification Name: needle, acupuncture, single use

3. Predicate Devices:
   Dong Bang Acupuncture Needles, (K972659)

4. Classifications Names & Citations:
   21CFR 880.5580, MQX, Acupuncture Needle, Class 2

5. Description:
   The KM Needles (Acupuncture Needle) are simple stainless steel pins that are used by an acupuncture practitioner in the treatment of various conditions. Acupuncture is the stimulation of specific acupuncture points along the skin of the body involving various methods such as penetration by thin needles or the application of heat, pressure, or laser light. Clinical practice varies depending on the country. Traditional acupuncture involves needle insertion, moxibustion, and cupping therapy. It is a form of alternative medicine and a key component of traditional Chinese medicine (TCM).

   The KM Needles (Acupuncture Needle) are constructed of stainless steel, with pin body diameters ranging from 0.16 to 0.70 mm and vary in length from 15 to 135 mm. Each acupuncture needle has a handle for the practitioner to manipulate the needle. The handle is also made from stainless steel and range in length from 20-30 mm.
6. Indication 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 state regulations.

7. Comparison with predicate device:
K.M.S Inc. believes that the KM Needles (Acupuncture Needle) is substantially equivalent to the Dong Bang Acupuncture Needles (K972659).

The predicate device chosen is comprised of the same material and both are single use devices delivered in a sterile condition. The predicate uses EO as the sterilization method and the KM Needles (Acupuncture Needle) are sterilized using radiation. Please note the table below, which demonstrates the similarities of the K.M.S Inc. Acupuncture Needles and the predicate device.

The table provides a comparison of the KM Needles (Acupuncture Needle) with the predicate device:

<table>
<thead>
<tr>
<th>Element of comparison</th>
<th>Subject Device</th>
<th>Claimed SE Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>K.M.S Inc.</td>
<td>Dong Bang Acupuncture Needle</td>
</tr>
<tr>
<td>FDA510(K) Number</td>
<td>N/A</td>
<td>K972659</td>
</tr>
<tr>
<td>Device Name</td>
<td>KM Needles (Acupuncture Needle)</td>
<td>ACUPUNCTURE NEEDLES</td>
</tr>
<tr>
<td>Intended Use</td>
<td>This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state regulations.</td>
<td>This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>General and hand type</td>
<td>General and hand type</td>
</tr>
<tr>
<td>Material:</td>
<td>STS 304</td>
<td>STS 304</td>
</tr>
<tr>
<td>- Needle body</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Handle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specification:</td>
<td>Length: 15~135mm</td>
<td>Length: 7~150mm</td>
</tr>
<tr>
<td>- Diameter</td>
<td>Diameter: 0.16~0.70mm</td>
<td>Diameter: 0.16~0.50mm</td>
</tr>
<tr>
<td>Tensile Strength of the</td>
<td>Diameter: 0.20 (723.3gf)</td>
<td>Diameter: 0.20 (709.6gf)</td>
</tr>
<tr>
<td>Acupuncture Needle</td>
<td>0.25 (726.6gf)</td>
<td>0.25 (673.6gf)</td>
</tr>
<tr>
<td></td>
<td>0.35 (733.3gf)</td>
<td>0.35 (686.3gf)</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Conform to ISO10993-1</td>
<td>Conform to ISO10993-1</td>
</tr>
<tr>
<td>Design</td>
<td>Spring</td>
<td>Spring</td>
</tr>
<tr>
<td>Reuse</td>
<td>Disposable, single use</td>
<td>Disposable, single use</td>
</tr>
<tr>
<td>Sterility</td>
<td>Gamma radiation</td>
<td>Sterilized by EO; SAL=10-6</td>
</tr>
</tbody>
</table>
The submitted K.M.S Inc. device and the predicate device have undergone testing to validate the tensile strength of the materials and also testing to verify the sterilization process and the sterile properties of the device, as delivered. The testing performed demonstrated that the devices met all of the criteria in these standards and that the submitted devices are similar in construction and delivered in the same state as the predicate Dong Bang acupuncture needles.

8. Performance Data:

9. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification K.M.S Inc. concludes that the KM Needles (Acupuncture Needle) are as safe and effective and substantially equivalent to predicate devices as described herein.

END