DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2015

K. S. Choi Corporation
Mr. Kak Soo Choi
President
179 W 39th Street
Los Angeles, California 90037-1015

Re: K142760
Trade/Device Name: AcuZone Acupuncture Needles, KSC DB Plus Acupuncture Needles, AcuZone Press Tack Needles, and AcuZone Intradermal Needles
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture needle
Regulatory Class: II
Product Code: MQX
Dated: May 8, 2015
Received: July 20, 2015

Dear Mr. Choi:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142760

Device Name
AcuZone Acupuncture Needles, KSC DB Plus Acupuncture Needles, AcuZone Press Tack Needles, and AcuZone Intradermal Needles

Indications for Use *(Describe)*
Our acupuncture needles are devices used by licensed practitioners and are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY
Traditional 510(k)
(As required by 21CFR 807.92)

August 24, 2015

Applicant: 807.92(a)

K. S. Choi Corporation
179 W. 39th St.
Los Angeles, CA 90037
Phone: 323-232-1600
Fax: 323-232-2747
Contact: Kak Soo Choi

Date Prepared: August 24, 2015

Device Name: AcuZone Acupuncture Needles, KSC DB Plus Acupuncture Needles, AcuZone Press Tack Needles, and AcuZone Intradermal Needles
Common Name: Acupuncture Needle
Classification Name: Acupuncture needle, Single Use
Product Code: MQX
Medical Specialty: General Hospital
Device Class: II
510(k) Number: **K142760**
Regulation Number: 880.5580

Predicate Device: 807.92(a)

The summary identifies the legally marketed device to which your firm is claiming equivalence:
(1) **Asia-med :** Asia-med Special + Needle (K031716) and (K042063)

Description of the Device 807.92(a) :

The acupuncture needles are sterile, 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 ethylene oxide gas. Acupuncture is the stimulation of specific acupuncture points along the skin of the body involving various methods such as penetration by thin needles. The skin is sterilized, such as with alcohol, and the needles are inserted, frequently with a plastic guide tube for the user. Needles may be manipulated in various ways including spinning, flicking, or moving up and down relative to the skin.
The Acuzone Acupuncture Needles and KSC DB Plus Acupuncture Needles are made of surgical stainless steel, a handle consisting of a flexible coiled copper handle with nickel plated for protection, or a surgical stainless steel or aluminum tube handle and may be provided with a plastic guide tube. (10pcs/pack, 1000pcs/box).
Acuzone press tack needles (with micropore tape) are made with surgical stainless steel (10pcs/ pack, 100pcs/box). AcuZone Intradermal Needles are made with surgical stainless steel (5pcs/pack, 100pcs/box).
Press tack and intradermal needles have same purpose for ear acupuncture point.

The Acupuncture needles are available in nine diameters (0.12 ~ 0.35mm), five needle lengths (15 ~ 60mm), and tube lengths (30mm, 45mm, 55mm, 65mm and 75mm).

Gauge (#)	**Diameter**	**Lengths**				
44	**.12mm**	**15mm**	**30mm**	**40mm**		
42	**.14mm**	**15mm**	**30mm**	**40mm**		
40	**.16mm**	**15mm**	**30mm**	**40mm**		
38	**.18mm**	**15mm**	**30mm**	**40mm**	**50mm**	
36	**.20mm**	**15mm**	**30mm**	**40mm**	**50mm**	**60mm**
34	**.22mm**	**15mm**	**30mm**	**40mm**	**50mm**	**60mm**
32	**.25mm**	**15mm**	**30mm**	**40mm**	**50mm**	**60mm**
30	**.30mm**	**15mm**	**30mm**	**40mm**	**50mm**	**60mm**
28	**.35mm**	**15mm**	**30mm**	**40mm**	**50mm**	**60mm**

Acuzone press tack needle is available in one diameter (0.20mm x 2mm x length (1mm).
AcuZone Intradermal Needles is available in one diameter (0.12mm), one length (5mm).

Intended Use of Device 807.92(a) :

Our acupuncture needles are devices used by licensed practitioners and are 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)

The acupuncture needle, as well as two predicate devices, Asia-med Special + Needle (K031716) and Asia-med Press Tack (K042063), were examined microscopically and mechanically tested to evaluate pull-out and elasticity properties. Specifically, the surfaces of the subject and predicate devices were found to be smooth and free of visible defects at 100X or higher magnification. Also the pull-out force of Acupuncture Needle was quantified and fell within the average values reported for the predicate devices. Finally, the elasticity properties of the subject device were found to be substantially equivalent to the two predicate devices, as after cantilever-type loading all devices returned to their original shape showing no permanent deformation.

Table 1: Comparison of Acuzone Acupuncture Needles, KSC DB Plus Acupuncture Needle, and Asia-med Special + Needle (K031716)

Device	**AcuZone and KSC DB Plus Acupuncture Needle**	**Asia-med Special + Needle 510(k) #K031716**
Indication for use	Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
Needle tip shape	Arrow	Arrow

Design	Stainless steel needle with a steel, aluminum or copper handle and a plastic guide tube for user	Stainless steel needle (+ silicon layer) with a copper handle and a copolymer (PET) guide tube.
Materials	Needle: surgical stainless steel Handle: metal (steel or aluminum tube or copper wire)	Needle: surgical stainless steel (+ silicon layer) Handle: copper
Sterility	Sterilized with ethylene oxide gas with residuals at a validated dose level	Sterilized with radiation at a validated dose level.
Needle (invasive)	Surgical stainless steel	Surgical stainless steel
Guide tube (non-invasive)	Polypropylene or PROVISTA™ Copolymer (PET)	PROVISTA™ Copolymer (PET)
Labeling	• Indication for use • Manufactured for or Distributed by • Product name • Acupuncture needles • Quantity • Size • Lot number • Expiration date • "Sterilized by ethylene oxide gas" • "For single use" • Discard any unused needle in the package after treatment session is completed. • "Made in China"	• Manufacturer's name and address • Product name • Acupuncture needles • Quantity • Size • Lot number • "Sterile" • Expiration date • "Sterilized by gamma radiation" • "For single use" • Rx statement • "Do not store at extreme temperatures and humidity" • "Do not use if package is previously opened or damaged" • "Made in Germany"
Available in Needle Diameters	0.12 mm, 0.14 mm, 0.16 mm, 0.18 mm, 0.20 mm, 0.22 mm, 0.25 mm, 0.30 mm, and 0.35 mm	0.20 mm, 0.25 mm, and 0.30 mm
Available in Needle Lengths	15 mm, 30 mm, 40 mm, 50 mm, and 60 mm	15 mm, 30 mm , and 40 mm

Table 2: Comparison of AcuZone Press Tack Needles, AcuZone Intradermal Needles, and Asia-med Press Tack (K042063)

Device	**AcuZone Press Tack Needles and AcuZone Intradermal Needles K142760**	**Asia-med Press Tack K042063**

Indication for use	Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
Needle tip shape	Arrow	Arrow
Design	 With or without tape for user	
Materials	Surgical stainless steel	Surgical stainless steel
Sterility	Sterilized	Sterilized
Available in Needle Diameters	Intradermal: 0.12 mm Press Tack: 0.20 mm	0.22 ~ 0.26 mm
Available in Needle Lengths	Intradermal: 5 mm Press Tack: 1 mm	1.6 ~ 1.8 mm

Our acupuncture needles are as safe and effective as the predicate, and are substantially equivalent to the predicate devices listed in this 510(k) submission; that is, the acupuncture needle has the same intended use (i.e., indications for use) and is similar, and in some cases the same, in both design (e.g., materials, sizes) and performance. The only difference is the quality of the product; for instance, the sharpness and the smoothness of the needle. Any differences in technological characteristics between the acupuncture needle and the predicate devices do not raise new issues of safety and effectiveness.

Non-clinical Performance Data 807.92(b)
Performance testing was conducted to evaluate and characterize the performance of the Acuzone and KSC DB Plus. Non-clinical data included dimensional conformance evaluation, visual inspections, and design verification to confirm biocompatibility testing based on the applicable elements of ISO 10993 series, which included the Material Mediated Pyrogen Testing using ISO 10993-11 and the EO and ECH Residuals Testing in accordance with ISO10993-7.

The EO Sterilization Validation, Sterility Testing, Bacterial Endotoxin Testing, Packaging Validation, and Long-Term Stability Testing were also performed.

Clinical Data 807.92(b)
Does not apply for these devices

Conclusion 807.92(b)
Biocompatibility tests and performance tests show that the device meets the requirements of those standards. Comparison with the predicate device shows that the device has similar specification and performance. Thus,

we conclude that Acuzone Acupuncture Needles, KSC DB Plus Acupuncture Needles, Acuzone Press Tack Needles, and Acuzone Intradermal Needles are substantially equivalent to the predicate device.

Kak Soo Choi, President

08/24/15

Date