DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 11, 2017

CHANGCHUN AIK MEDICAL DEVICES CO., LTD
Mr. Xingwang Li
General Manager
No. 25, Karen Industrial Park, Jiutai Economic Development Zone
Changchun, Jilin 130507
CHINA

Re: K162566
Trade/Device Name: AIK Sterile Acupuncture Needles for Single Use
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture needle
Regulatory Class: Class II
Product Code: MQX
Dated: September 8, 2016
Received: April 10, 2017

Dear Mr. Xingwang Li:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K162566

Device Name
AIK Sterile Acupuncture Needles for Single Use

Indications for Use *(Describe)*
The AIK Sterile Acupuncture Needles for Single Use 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K162566

510(k) Summary

Submitter: CHANGCHUN AIK MEDICAL DEVICES CO., LTD
No. 25, Karen Industrial Park, Jiutai Economic Development Zone, Changchun, Jilin Province, 130507

Contact: Mr. Li, Xingwang
General Manager
Phone: (86)-13364688867 /
(86)-18616806984
Email: aik2000@163.com

Date Prepared: May, 4 2017

Device Trade Name: AIK Sterile Acupuncture Needles for Single Use

Device Common Name: Acupuncture Needle

Classification Name: Acupuncture Needle

Class: II

Regulation Number: 880.5580

Panel: General Hospital and Personal Use Devices

Product Code: MQX

1. Predicate Device:

Device	Company	Product Code	510(k) Number
SMC Acupuncture Needle	SMC.	MQX	K141473

3. Indications for Use:

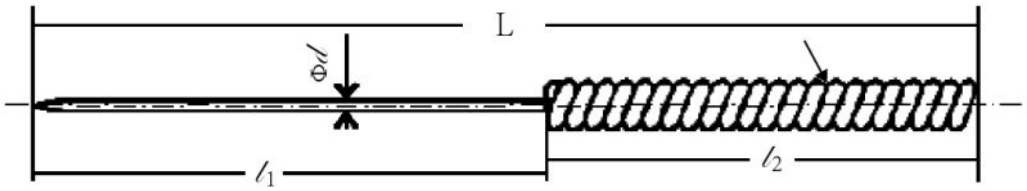
The AIK Sterile Acupuncture Needles for Single Use is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

3. Product Description:

The Acupuncture Needles are manufactured from stainless steel and sterilized with ethylene oxide gas. Acupuncture needle is made up of needle handle and needle body. The body of needle uses 304 stainless steel wire (06Cr19Ni10). The handle is a body coil with stainless steel wire, the spiral loop of which is arranged symmetrically without gaps.

The device can only be used by qualified practitioners of acupunctures. Qualified practitioners should already be knowledgeable on how to use the acupuncture needle and when not to use acupuncture in certain patient populations and medical conditions.

Handle of acupuncture needle is a plain handle. Types of acupuncture needle (sterile acupuncture needle for single use) are: acupuncture needle without a guide tube and acupuncture needle with a guide tube.



Product Specification

Diameter specification of acupuncture needle: Ø 0.14mm-Ø 0.35mm; length specification of needle body: 13mm-75mm.

Gauge (#)	Diameter	Lengths of needle body							
42G	0.14mm	13mm	15mm	25mm					
40G	0.16mm	13mm	15mm	25mm	30mm				
38G	0.18mm	13mm	15mm	25mm	30mm	40mm			
36G	0.20mm	13mm	15mm	25mm	30mm	40mm	50mm		
34G	0.22mm	13mm	15mm	25mm	30mm	40mm	50mm	60mm	
32G	0.25mm	13mm	15mm	25mm	30mm	40mm	50mm	60mm	75mm
30G	0.30mm	13mm	15mm	25mm	30mm	40mm	50mm	60mm	75mm
28G	0.35mm	13mm	15mm	25mm	30mm	40mm	50mm	60mm	75mm

4. Non-Clinical Testing

Performance testing was conducted to evaluate and characterize the performance of the AIK Sterile Acupuncture Needles. Non-clinical data included dimensional evaluation, and performance requirements evaluation per international standard, ISO 17218. Material performances are evaluated per international standard ISO 10993-1. In detail, the needle body needle handle, and guide tube were tested by tests of in vitro cytotoxicity, intracutaneous reactivity/irritation, skin sensitization and pyrogen. And the needle body were further tested by tests of hemodialysis study, and systemic toxicity study. All biocompatibility tests results show that the subject device is biocompatibility safe.

The primary package performance are evaluated per international standard ISO 11607. EO sterilization process are evaluated per international standard ISO 11135. And the EO and ECH Residuals Testing in accordance with ISO10993-7.

The EO Sterilization Validation, Sterility Testing, Packaging Validation, and Long-Term Stability Testing were also performed per relevant standards.

All the test results demonstrate AIK Sterile Acupuncture Needles for Single Use meet the requirements of its pre-defined acceptance criteria and intended uses.
For example, the function performance tests including:

- Appearance and cleanliness tests
- Drawing strength test
- Needle body hardness test
- Resistance to breakage of needle body test
- Intensity and puncture performance of needle tip test
- Sterile Test
- Resistance to corrosion test

5. Substantial Equivalence Determination

The indications for use and technology characteristics of the proposed AIK Sterile Acupuncture Needles for Single Use, and the substantial equivalence to the predicate devices have been demonstrated via data collected in design verifications. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its indications for use. The subject device is substantial equivalent to the predicate device.
The comparison to predicate devices as below table.

Comparison to Predicate Devices

Item	Proposed Device (AIK Sterile Acupuncture Needles for Single Use)	Predicate Device (SMC Acupuncture Needle)
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
Applied types	Needle with/without plastic guide tube	Needle with/without plastic guide tube
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 with a steel, aluminum or copper handle and a plastic guide tube for user
Materials	Needle: surgical stainless steel (SUS304); Handle: metal (steel); Coating material: Polydimethylsiloxane; Guild Tube(not contact): PVC; following ISO 10993-1 for cytotoxicity test sensitization test	Needle: surgical stainless steel (SUS304) Handle: metal (steel or aluminum tube or copper wire) Coating material: Polydimethylsiloxane; Guild Tube(not contact): PVC; following ISO 10993-1 for cytotoxicity test

		intracutaneous reactivity test； hemodialysis study； systemic toxicity study； Pyrogen and Endotoxins study;	sensitization test and intracutaneous reactivity test
Sterility		Sterilized with ethylene oxide gas with residuals at a validated dose level	Sterilized with ethylene oxide gas and or / Sterilized by Gamma Irradiation
Available in Needle Diameters		0.14 mm, 0.16 mm, 0.18 mm, 0.20 mm, 0.22 mm, 0.25 mm, 0.30 mm, 0.35 mm	0.16 to 0.70 mm
Available in Needle Lengths		13 mm, 15 mm, 25 mm, 30 mm, 40 mm, 50 mm, 60 mm, 75 mm	15-135 mm
Labeling		Comply to 21 CFR 801	Comply to 21 CFR 801
Performance Requirements	**Appearance and Cleanliness**	Examined under corrected-to-normal vision, and x 10 magnification: Comply to the requirements specified is ISO 17218	Examined under corrected-to-normal vision, and x 10 magnification: Comply to the requirements specified is ISO 17218
	Drawing strength	Needle solidly joined after the test following ISO 17218, clause 5.3.2	Needle solidly joined after the test following ISO 17218, clause 5.3.2
	Hardness of the needle body	Hardness of needle body comply the requirements specified in ISO 17218, clause 5.3.3	Hardness of needle body comply the requirements specified in ISO 17218, clause 5.3.3
	Resistance to breakage of the needle body	The body of the needle is sufficient resistance to breakage after test following ISO 17218, clause 5.3.4	The body of the needle is sufficient resistance to breakage after test following ISO 17218, clause 5.3.4
	Intensity and puncture performance	The tip of the needle has good intensity and puncture performance following the tests specified in ISO 17218, clause 5.3.5	The tip of the needle has good intensity and puncture performance following the tests specified in ISO 17218, clause 5.3.5
	Resistance to corrosion	No corrosion of the body of the needle following the test specified in ISO 17218, clause 5.3.6	No corrosion of the body of the needle following the test specified in ISO 17218, clause 5.3.6

The subject device acupuncture needles are substantially equivalent to the predicate device 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. One difference is the available needle diameters and needle lengths. Another difference is that our acupuncture needle claims for EO sterilization only, and the predicate device claims for both EO sterilization and Gamma irradiation sterilization methods.

6. Conclusion

Based on the indications for use, technological characteristics and performance testing, the AIK Sterile Acupuncture Needles for Single Use has demonstrated to be substantially equivalent to the predicate device.