May 21, 2021

SMTP Technology Co., Ltd
℅ Randy Jiang
Sr. consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K202299
Trade/Device Name: Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: April 13, 2021
Received: April 19, 2021

Dear Randy Jiang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202299

Device Name
Ultrasonic Surgical Aspirator System

Indications for Use *(Describe)*
The XD880B Ultrasonic Surgical Aspirator System is an ultrasonic surgical system consisting of handpieces and associated tips. The product is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone and bone approximations) tissue, the intended use is as follows with different configurations:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological surgery
- Plastic and Reconstructive surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Wound Care
- Laparoscopic Surgery
- Thoracoscopic Surgery

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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510(k) Summary

Ultrasonic Surgical Aspirator System

1. Submission Sponsor

SMTP Technology Co., Ltd.
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Contact: Songtao Zhan
Title: CTO
Phone number: +86-10-88572898

2. Submission Correspondent

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2500 Bee Cave Road
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Austin, TX 78746
Office Phone: (512) 327-9997
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Contact: Randy Jiang
Title: Senior Consultant

3. Date Prepared

May, 19th, 2021

4. Device Identification

Trade/Proprietary Name:	Ultrasonic Surgical Aspirator System
Common/Usual Name:	Ultrasonic Surgical Aspirator
Classification Name:	instrument, ultrasonic surgical
Regulation Number:	N/A, Pre-Amendment
Product Code:	LFL
Class:	Unclassified
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

	K#	Name	Manufacturer
Primary Predicate Device	K070313	Alliger Ultrasonic Surgical System Model AUSS-7	Misonix Inc.
Secondary Predicate Device	K062471	FS 1000 RF Ultrasonic Surgical Aspirator System and Accessories	Misonix Inc.
Reference Device	K172464	XD880A Ultrasonic Osteotomy Surgical System	SMTP Technology Co., Ltd

6. Indication for Use Statement

The XD880B Ultrasonic Surgical Aspirator System is an ultrasonic surgical system consisting of handpieces and associated tips. The product is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone and bone approximations) tissue, the intended use is as follows with different configurations:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Wound Care
- Laparoscopic Surgery
- Thoracoscopic Surgery

7. Device Description

The XD880B Ultrasonic Surgical Aspirator System is an ultrasonic powered surgical tool. It can be used for precise breakage, aspiration and debridement of soft tissue, and can also be used for precise cutting, crushing and shaping of bone tissue. The product can be applied to a number of departments by using the suitable parameters and accessories, including:

- Department of Neurosurgery, general surgery and other departments for soft tissue cutting, breakage and aspiration.
- Department of Orthopedic surgery, Plastic and Reconstructive surgery, Department of Neurosurgery (only for bone) for bone cutting.
- As well as the Department of Dermatology, Department of Trauma Orthopedics and other departments used for debridement.

The XD880B Ultrasonic Surgical Aspirator System consists of a console, foot switch, and accessories. The accessories include handpiece, tips, wrench, liquid-flow sleeve, liquid-flow tube, sterilization tray, suction bag, suction canister and mobile cart. The handpiece, tips, liquid-flow sleeve and liquid-flow tube are assembled into ultrasonic tool part to complete the cutting and fragment of bone tissue and soft tissues.

8. Substantial Equivalence Discussion

The following Table 1 compares the Ultrasonic Surgical Aspirator System to the predicate devices with respect to intended use, power supply, product classification, irrigation, aspiration system, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate devices.

Table 1 – Comparison of Characteristics

Attribute	Subject device	Primary Predicate Device (K070313)	Secondary Predicate Device (K062471)
Manufacturer	SMTP Technology Co., Ltd.	Misonix Inc.	Misonix Inc.
Classification	Unclassified	Unclassified	Unclassified
Common/Usual Name	Ultrasonic Surgical Aspirator Ultrasonic Surgical System	Ultrasonic Surgical Aspirator Ultrasonic Surgical System	Ultrasonic Surgical Aspirator Ultrasonic Surgical System
Regulation Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Product Code	LFL	LFL	LFL
Indications for Use	The XD880B Ultrasonic Surgical Aspirator System is an ultrasonic surgical system consisting of	The Misonix Inc. AUSS-7 Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of both soft and	The Misonix Inc. FS 1000 RE Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification and

	handpieces and associated tips. The product is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone and bone approximations) tissue, the intended use is as follows with different configurations: ● Neurosurgery ● Gastrointestinal and Affiliated Organ Surgery ● Urological Surgery ● Plastic and Reconstructive Surgery ● General Surgery ● Orthopedic Surgery ● Gynecological Surgery ● Thoracic Surgery ● Wound Care ● Laparoscopic Surgery ● Thoracoscopic Surgery	hard (e.g.: bone) tissue in the following surgical specialties: ● Neurosurgery ● Gastrointestinal and Affiliated Organ Surgery ● Urological Surgery ● Plastic and Reconstructive Surgery ● General Surgery ● Orthopedic Surgery ● Gynecology ● Thoracic Surgery ● Wound Care	aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties: ● Neurosurgery ● Gastrointestinal and Affiliated Organ Surgery ● Urological Surgery ● Plastic and Reconstructive Surgery ● General Surgery ● Orthopedic Surgery ● Gynecological Surgery ● Thoracic Surgery ● Laparoscopic Surgery ● Thoracoscopic Surgery The system may also be combined with electrosurgery using optional RF Surgery interface components.
Vibration System	Continuous Wave Frequency: 39kHz & 52kHz	Continuous Wave Frequency: 22.0-24.5 kHz	Continuous Wave Frequency: 23+/-1 kHz or 22-24 kHz
Electrical Power Supply	100-240 VAC 50/60 Hz.	100-130 VAC 6.5 Amps, 50/60 Hz 200/250 VAC 2.25 Amps, 50/60 Hz	115 VAC and 230 VAC 50/60Hz

Power Input Current	3.6A max	6.5A at 100-130 VAC, 3.25A at 200/250 VAC	4A max
Footswitch	Foot switch connected to the device control unit by means of a cord.	Wired (connected to rear panel of console), Single pedal footswitch to activate delivery of ultrasound and irrigation	Wired - On/Off Pedal for amplitude, irrigation and aspiration - Flush Button - COAG with CUT lockout feature - COAG simultaneous with ultrasound - COAG only
Console	The functional parameters are displayed and controlled through a console with touch screen.	Console with membrane control panel and graphical user interface	Console with membrane control panel and LED indicators.
Device contains Software	Yes	Yes	Yes
Irrigation System	Peristaltic pump.	Peristaltic pump	Peristaltic pump
Irrigation fluid	Adjustable between: 5 to 120 ml/min.	Adjustable: 0 - 100 ml/min	Up to 10cc/min
Aspiration Vacuum	600mmHg (80kPa) maximum	Max: 28” Hg Max	Min: less than 0.5” Hg Max: 25” Hg
Dimensions	18.0cm H ×31.0cm W × 53.5cm D	18.0cm H x 41.0cm W x 68.5cm D	102cm H x 63.5cm W x 48cm D
Weight	9.3kg	11.6 kg	54.5 kg

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of XD880B Ultrasonic Surgical Aspirator System and to show substantial equivalence to the predicate devices, SMTP Technology Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The XD880B Ultrasonic Surgical Aspirator System passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate devices:

- Electrical safety testing per IEC 60601-1 - Passed
- EMC testing per IEC 60601-1-2 - Passed
- Software verification and validation per IEC 62304/FDA Guidance - Passed
- Moist heat sterilization validation per ISO 17665-1- Passed
- EO sterilization validation per ISO 11135 - Passed, demonstrates SAL of 10^{-6}
- Shelf-life Testing - Passed
- Lifetime validation test for handpieces - Passed
- Acoustic Performance Test per IEC61847 - Passed
- Efficiency and Temperature Characteristics Test - Passed

10. Clinical Performance Data

Not applicable.

11. Statement of Substantial Equivalence

The XD880B Ultrasonic Surgical Aspirator System has the same intended use as the predicate devices, and the same or similar indications and technological characteristics. The differences do not raise new or different questions of safety and effectiveness. Electrical safety and performance testing have demonstrated the XD880B Ultrasonic Surgical Aspirator System is as safe and effective as the predicate devices. Therefore, the XD880B Ultrasonic Surgical Aspirator System is substantially equivalent to the predicate devices.