September 27, 2021

SMTP Technology Co., Ltd.
Songtao Zhan
CTO
1F&4F, Building A, Emerging Industry Incubation Center
Zhangjiagang Free Trade Zone, 215634
Jiangsu Province
China

Re: K212750
Trade/Device Name: Ultrasonic Surgical Aspirator System, Model: XD880B
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 26, 2021
Received: August 30, 2021

Dear Songtao Zhan:

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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2021.09.27 15:18:39 -04'00'

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)*
K212750

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. Date Prepared

Sep. 27th, 2021

2. Submitter's Information

Company Name:	SMTP Technology Co., Ltd.
Company Address:	1F&4F, Building A, Emerging Industry Incubation Center, Zhangjiagang Free Trade Zone, 215634, Jiangsu Province, CHINA
Fax:	+86 10 88572898 ext. 8005
Contact Person:	Songtao Zhan CTO Tel: +86 10 88572898 zhansongtao@smtpmed.com

3. Trade Name, Common Name, Classification

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:	Class II
Classification Panel:	General & Plastic Surgery

4. Identification of Predicate Devices(s)

The identification of predicate device within this submission is as follow:

Manufacturer:	SMTP Technology Co., Ltd.
Trade Name:	Ultrasonic Surgical Aspirator System

Classification Name:	instrument, ultrasonic surgical
Regulation Number:	N/A, Pre-Amendment
Product Code:	LFL
Class:	Class II
Classification Panel:	General & Plastic Surgery
FDA 510 (k) #:	K202299

5. Description of the Device

The Ultrasonic Surgical Aspirator System (Model: XD880B) is an ultrasonic powered surgical tool. It can be used for precise breakage, aspiration and debridement of soft tissues, and can also be used for precise cutting, crushing and shaping of bone tissue, using with the liquid-flow sleeve and liquid-flow tube. The product can be applied to a number of departments according to the suitable parameters and accessories, including:

- Department of Neurosurgery, general surgery and other departments for soft tissue 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 Ultrasonic Surgical Aspirator System consists of a console, application software, foot switch, and accessories. The accessories include handpieces, tips, wrenches, liquid-flow sleeves, liquid-flow tubes, sterilization tray, suction bag, suction canister and mobile cart. The handpiece, tip, liquid-flow sleeve and liquid-flow tube assemble to ultrasonic tool part to complete the cutting and fragment of soft tissue and bone tissue.

6. Indications for Use

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. Substantial Equivalence

Most the features and characteristics of the subject device Ultrasonic Surgical Aspirator System are identical to those of the predicate device under k202299, and where there are differences, such differences do not have an impact on the safety or effectiveness of the subject device.

The following Table 7A compares the subject device Ultrasonic Surgical Aspirator System to the predicate device.

Table 7A – Comparison of Characteristics

State	SUBJECT DEVICE	PREDICATE DEVICE K202299
Manufacturer	SMTP Technology Co., Ltd.	SMTP Technology Co., Ltd.
Classification	Unclassified	Unclassified
Common/Usual Name	Ultrasonic Surgical Aspirator Ultrasonic Surgical System	Ultrasonic Surgical Aspirator Ultrasonic Surgical System
Regulation Panel	General & Plastic Surgery	General & Plastic Surgery
Product Code	LFL	LFL
Indications for Use	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	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	General Surgery Orthopedic Surgery Gynecological Surgery Thoracic Surgery Wound Care Laparoscopic Surgery Thoracoscopic Surgery
Vibration System	Continuous Wave Frequency: 39kHz & 52kHz	Continuous Wave Frequency: 39kHz & 52kHz
Electrical Power Supply	100-240 VAC 50/60 Hz.	100-240 VAC 50/60 Hz.
Footswitch	Foot switch connected to the device control unit by means of a cord.	Foot switch connected to the device control unit by means of a cord.
Console	The functional parameters are displayed and controlled through a console with touch screen.	The functional parameters are displayed and controlled through a console with touch screen.
Irrigation System	Peristaltic pump.	Peristaltic pump.
Irrigation fluid	Adjustable between: 5 to 120 ml/min.	Adjustable between: 5 to 120 ml/min.
Aspiration Vacuum	600mmHg (80kPa) maximum	600mmHg (80kPa) maximum
Soft Tissue Protection in Bone Cutting Mode	Yes	No
Blade with Slot of Cutting Tips	With slot	Without slot.
Dimensions	18.0cm H ×31.0cm W × 53.5cm D	18.0cm H ×31.0cm W × 53.5cm D
Weight	9.3kg	9.3kg

Discussion of Substantial Equivalence:

Comparison of General information, Product performance, Electrical characteristics, and Conditions between the predicate device and the subject device is identified minor differences; the differences were supported with safety and performance testing, as appropriate, and do not affect device safety and performance. The subject device has same indications for use with predicate device. The technological characteristics differences listed

in the above table between the subject device and the predicate device do not raise any new harms of safety and effectiveness.

Non-Clinical Performance Data:

SMTP completed the following non-clinical tests to demonstrate safety and effectiveness of Ultrasonic Surgical Aspirator System to show substantial equivalence to the predicate device, the test results confirm that the performance specifications meets the modification inputs.

Bench Testing

- Safety and Performance Testing for Soft Tissue Protection in Bone Cutting Mode.
- Acoustic Performance Testing for modified tips.
- Cutting Efficiency and Thermal testing Report for Modified Tips.
- Comparison of Substantial Equivalence for Modified Tips.

Clinical Performance Data:

Clinical evaluation is not applicable for the proposed device.

8. Conclusion

The Ultrasonic Surgical Aspirator System has the same intended use as the predicate device, and the same or similar technological characteristics. The differences in technological characteristics do not raise new harms of safety and effectiveness. Safety and performance testing have demonstrated the Ultrasonic Surgical Aspirator System is as safe and effective as the predicate device. Therefore, the subject device Ultrasonic Surgical Aspirator System is substantially equivalent to the predicate device.