SMTP Technology Co., Ltd
Songtao Zhan
Contact Address1F&4F, Building A, Emerging Industry Incubation Center
Zhangjiagang, Jiangsu 215634
China

February 19, 2021

Re: K201274
Trade/Device Name: Ultrasonic Osteotomy Surgical System
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: Class II
Product Code: JDX
Dated: January 9, 2021
Received: January 21, 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,

For Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201274

Device Name
Ultrasonic Osteotomy Surgical System

Indications for Use *(Describe)*
Ultrasonic Osteotomy Surgical System is an ultrasonic surgical system consisting of a handpiece and associated tips for cutting bone, osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to:
- Otolaryngology
- Oral/maxillofacial
- Hand and foot
- Neurosurgery
- Spine
- Plastic/reconstructive.

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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Ultrasonic Osteotomy Surgical System
510 (k) Summary

1. Date Prepared

February 19th, 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 Name:	Ultrasonic Osteotomy Surgical System
Classification Name:	Sonic Surgical instrument and accessories/attachments
Product Code:	JDX
Regulation Number:	21 CFR 888.4580
Device Class:	Class II

4. Identification of Predicate Devices(s)

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

Manufacturer:	SMTP Technology Co., Ltd.
Trade Name:	XD880A Ultrasonic Osteotomy Surgical System
Product Code:	JDX

Classification Name:	Sonic Surgical instrument and accessories/attachments
Regulation Number:	21 CFR 888.4580
FDA 510 (k) #:	K172464

5. Description of the Device

Ultrasonic Osteotomy Surgical System uses ultrasonic technology to generate mechanical micro-vibrations of the tip insert connected to the handpiece, the piezoelectric transducer converting the electrical voltage supplied by the ultrasonic generator into mechanical energy that induces vibration of the tip insert at the resonant frequency of the cutting tip insert. The tips are used to fragment and reshape bone tissue through longitudinal vibration at high frequency and small amplitude.

Ultrasonic Osteotomy Surgical System consists of a console (control unit) with an integrated peristaltic pump, a handpiece with a connecting cord, a range of cutting tips, wrench and torque wrench, a foot switch and irrigation set (liquid-flow tube and liquid-flow sleeve).

The console has a color LCD touch screen user interface for the selection/visualization of device functional parameters. The console activates and controls the ultrasound vibration, controls irrigation flow and displays system condition.

The console is connected to the main power by an electrical cord. It includes connectors for the handpiece and for the footswitch. The console incorporates a peristaltic pump which provides, through the irrigation tubing set, a sterile fluid supply to the surgical site. Ultrasonic power and irrigation flow to the handpiece are simultaneously activated by pressing the footswitch. The handpiece contains a piezoelectric ultrasonic transducer which attaches to the generator (inside the console) by a cable at one end of the handpiece. Tip inserts are attached to the other end of the handpiece.

6. Indications for Use

Ultrasonic Osteotomy Surgical System is an ultrasonic surgical system consisting of a handpiece and associated tips for cutting bone, osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to:

- Otolaryngology
- Oral/maxillofacial
- Hand and foot
- Neurosurgery
- Spine
- Plastic/reconstructive

7. Substantial Equivalence

Most the features and characteristics of proposed Ultrasonic Osteotomy Surgical System (subject device) are identical to those of the predicate device (K172464), and where there are differences, such differences do not have impact on the safety or effectiveness of the subject device.

The following table compares the subject device Ultrasonic Osteotomy Surgical System to the predicate device.

Table 1 – Comparison of Characteristics

State	Subject Device	Predicate Device	Comparison
General Description			
Manufacturer	SMTP Technology Co., Ltd.	SMTP Technology Co., Ltd.	Same
Composition	The device consists of a console, foot switch and accessories. The accessories include handpiece, liquid-flow tube, liquid-flow sleeve, wrench and an assortment of cutting tips.	The device consists of a console, foot switch and accessories. The accessories include handpiece, liquid-flow tube, liquid-flow sleeve, wrench and an assortment of cutting tips.	Same
Indications for Use	Ultrasonic Osteotomy Surgical System is an ultrasonic surgical system consisting of a handpiece and associated tips for cutting bone, osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to: - Otolaryngology - Oral/maxillofacial - Hand and foot - Neurosurgery - Spine - Plastic/reconstructive	Ultrasonic Osteotomy Surgical System is an ultrasonic surgical system consisting of a handpiece and associated tips for cutting bone, osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to: - Otolaryngology - Oral/maxillofacial - Hand and foot - Neurosurgery - Spine - Plastic/reconstructive	Same
User Interface	The functional parameters are displayed and controlled through a console with touch	The functional parameters are displayed and controlled through a console with touch	Same

	screen.	screen.	
Ultrasonic vibration activation	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.	Same
Irrigation System	Peristaltic pump The placement of pump is vertical	Peristaltic pump The placement pump is horizontal	Similar The subject device has the same type peristaltic pump with the predicate device. The difference is placement direction of the pump. The direction change does not impact the flow rate parameter.
Wrench type	Torque wrench; Normal wrench	Normal wrench	Similar The new torque wrench has the same material and function with the normal wrench. The torque wrench does not contact patients.
Tip material	Titanium alloy	Titanium alloy	Same
Sterilization Method	EO for disposable components Moist heat for reusable components	Moist heat	Similar The subject device provides sterilized packaging by EO sterilization for disposable components. The sterilization methods and parameters of all components have been verified and confirmed.
Performance Description			
Frequency	39 kHz±4kHz	39 kHz±4kHz	Same
Maximum flow	120ml/min±20%	120ml/min±20%	Same
Ultrasound output mode	Continuous or pulsed mode	Continuous or pulsed mode	Same
Electrical Description			

Electrical Safety Classification	Class I, Type BF Applied Part	Class I, Type BF Applied Part	Same
Power supply	100-240 VAC, 50/60 Hz.	100-240 VAC, 50/60 Hz.	Same
Power cord length	About 3m	About 3m	Same
Conditions Description			
Operating environment conditions	Environment Temperature:10℃ ~30℃ Relative Humidity: 30%~75%, no condensation Atmospheric pressure: 700hPa~1060hPa	Environment Temperature:10℃ ~30℃ Relative Humidity: 30%~75%, no condensation Atmospheric pressure: 700hPa~1060hPa	Same
Shipping and storage conditions	Environment Temperature: -30℃ ~ 50℃ Relative Humidity: ≤ 90%, no condensation Atmospheric pressure: 700hPa~1060hPa	Environment Temperature: -30℃~50℃ Relative Humidity: ≤ 90%, no condensation Atmospheric pressure: 700hPa~1060hPa	Same

Discussion of Substantial Equivalence:

Comparison of General information, Product performance, Electrical characteristics, and Conditions between the predicate device and the subject device Ultrasonic Osteotomy Surgical System, minor differences with the Predicate device was identified. The differences were supported with safety and performance testing, as appropriate, and are not likely to affect device safety and performance. The subject device has same indications for use. The technological characteristics differences listed in the above table between the subject device and the predicate device do not raise any new questions of safety and effectiveness.

Non-Clinical Performance Data:

SMTP completed the following non-clinical tests to demonstrate safety and effectiveness of Ultrasonic Osteotomy Surgical System and to show substantial equivalence to the predicate device, the test results confirm that the design inputs and performance specifications for the Ultrasonic Osteotomy Surgical System are met.

Sterilization and Shelf Life

Single Use Disposable Components – Sterile packaging provided

Cutting tip, liquid-flow tube and liquid-flow sleeves are provided sterile and are for single use. The submission includes EO sterilization validation tests for sterile package.

The submission also includes sterile barrier testing, device performance testing on sterilized, simulated shipment testing, accelerated and natural aged testing to support the claimed shelf life.

Reusable Components – End user cleaned and sterilized

The reusable handpiece and wrenches are cleaned and sterilized by end user before each use. The cleaning and sterilization testing for each reusable component are performed.

Bench Testing

- Ultrasound Performance Testing
- Irrigation Performance Testing
- Cutting Efficiency and Thermal Testing
- Mechanical Testing for Torque Wrench

Clinical Performance Data:

Clinical evaluation is not applicable for the proposed device.

8. Conclusion

The Ultrasonic Osteotomy Surgical 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 or different questions of safety and effectiveness. Safety and performance testing have demonstrated the Ultrasonic Osteotomy Surgical System is as safe and effective as the predicate device. Based on the information contained within this submission, it is concluded that the Ultrasonic Osteotomy Surgical System is substantially equivalent to the predicate device which is already in commercial distribution in the United States.