



April 24, 2018

Morley Research Consortium
Dr. Suzan Davis, Pharm. D, RAC, EMBA, CQA
Head of Regulatory Affairs and Compliance
Four Concourse Parkway Suite 215
Atlanta, Georgia 30328

Re: K172464

Trade/Device Name: XD880A Ultrasonic Osteotomy Surgical System
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic Surgical Instrument and Accessories/Attachments
Regulatory Class: Class II
Product Code: JDY, DZI, ERL, HBE, HWE
Dated: March 15, 2018
Received: March 22, 2018

Dear Dr. Davis:

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.

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jennifer R.
Stevenson -S3**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172464

Device Name

XD880A Ultrasonic Osteotomy Surgical System

Indications for Use (Describe)

XD880A 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.

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510(k) Summary in accordance with 21 CFR 807.92

1. Administrative Information

Type of 510(k) submission: Traditional

Submission Date: July 31st, 2017

510(k) Submitter: SMTP Technology Co., Ltd.
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Manufacturer: SMTP Technology Co., Ltd.
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SMTP Technology Co., Ltd.

2. Device

Proprietary Name: XD880A Ultrasonic Osteotomy Surgical System

Regulation Number: 21 CFR 888.4580

Device Classification Name: Sonic Surgical instrument and accessories/attachments

Regulation Identification: A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip, that vibrate at high frequencies, and it is intended for medical purposes to cut bone or other materials, such as acrylic.

Regulation Medical Specialty: Orthopedic

Classification product codes: JDX
DZI, ERL, HBE, HWE

Device Class: Class II

3. Predicate Devices

The substantial equivalence of the subject device is based on the following legally marketed predicate devices

Trade Name	Manufacturer	Product Code	510(k) Number	Decision Date
Piezosurgery Flex	MECTRON Spa	JDX, DZI, ERL, HBE, HWE	K132848	29 November 2013
Piezoelectric System	SATELECT-Acteon Group	JDX, DZI, ERL, HBE, HWE	K100410	28 April 2010

4. Device Description

XD880A Ultrasonic Osteotomy Surgical System consists of a console (control unit) with an integrated peristaltic pump, a handpiece with a connecting cord, a range of tip inserts, a torque wrench, a footswitch and an 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. Inside the console are located the ultrasonic generator, the electrical power supply module and the micro-processor electronic board that controls and supervises the functional parameters of the device.

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.

XD880A Ultrasonic Osteotomy Surgery 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 tip insert.

The tips are used to fragment and reshape bone tissue through longitudinal vibration at high frequency and small amplitude (less than 0.12mm), while keeping the soft tissues with elastic properties and free of damage.

5. Intended Use

XD880A Ultrasonic Osteotomy Surgical System is an ultrasonic surgical system that includes a handpiece and associated cutting tips intended for osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to:

- Otolaryngology
- Oral/maxillofacial
- Hand and foot
- Neurosurgery (bone only)
- Spine
- Plastic/reconstructive.

6. Performance Testing

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the XD880A Ultrasonic Osteotomy Surgical System. The system complies with the IEC 60601-1:2006 standards for safety and the IEC 60601-1-2:2007/2010 standard for EMC.

Biocompatibility

XD880A Ultrasonic Osteotomy Surgical System components that come into direct contact with patients during surgical procedures are the handpiece and tips inserts. According to ISO 10993-1, these components are classified as ‘external communicating devices’, as they get in contact with ‘tissue/bone/indirect blood path’ for a duration less than 24 hours (≤ 24 h). The cutting tips are made of Titanium Alloy TC4 which meets the requirements of ISO 5832-2:1999 and ISO 5832-3:1996).

The other system components that can have indirect contact with the surface of patient’s body during surgery are liquid-flow sleeve and liquid-flow tube, and the duration of their contact is less than 24 hours (≤ 24 hours). Liquid-flow sleeve and liquid-flow tube are made of Medical Silicone Rubber that meets the requirements of JISK 6249:2003.

Biocompatibility studies have been conducted on Titanium Alloy TC4 and Medical Silicone Rubber and studies results showed that both materials are biocompatible.

Software Verification and Validation

XD880A Ultrasonic Osteotomy Surgery System Software verification and validation testing were conducted in line with the requirements of FDA Guidance ‘Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices’, 11 May 2005. The software for this device was considered as a “moderate level of concern “ and software verification and validation reports have been included in this submission.

Mechanical and Acoustic Testing

Bench testing and acoustic testing were conducted on the subject device. Testing results demonstrated that the subject device performs within its specifications.

Animal Study

A GLP animal study has been conducted with the 15 types of tips on 10 beagles. The objective of the study was to evaluate the efficiency, convenience and safety of the 15 tips during spine surgery. Animals were split into two groups of 5 animals each. The 15 types of tips were split between the two groups of animals. All animals were anesthetized with pentobarbital sodium and were cut at T11-T13 thoracic vertebral posterior and vertebral plate to reduce the pressure. Each animal was cut at T12 spinous process at the mid-line and cut through the subcutaneous tissue. After separating the attached dorsal muscles from the spinous process, the vertebral plate and T11-T13 flat joints, the vertebral plate was cut with XD880A Ultrasonic Osteotomy Surgical Tips.

All the operating procedures were performed in the same conditions and with same system parameters (power: level 5, pulse: level 6, wash flow: level 4). The set-up parameters were at their maximum value to evaluate the efficiency and safety of the tips when operating at the maximum conditions.

The tips' efficiency was evaluated by analyzing the cutting time of the bone and bleeding volume when using each tip on the animals. The tips' safety was evaluated by monitoring and recording neurophysiological parameters of each animal prior, during and after the surgery. The Sensory Evoked Potential (SEP) latent period and fluctuation, and Motor Evoked Potential (MEP) were used to evaluate the neurophysiological parameters. SEP and MEP values were recorded for both back legs and vertebral plate before the operation (Phase I), at the start of the cutting process (Phase II), after exposure of spinal dura mater (Phase III) and after the end of operation (Phase IV). Additionally, a clinical observation of animals' mental state and behavior was performed on all animals on day 1, day 3 and day 7 after operation. CT scan was performed on day 7 and histopathology was performed on day 8 after operation.

Study results demonstrated that all tips were efficient and safe when used at the recommended conditions. The average cutting time was 12min and 2 second and 10min and 24 second in the first and second group of animals respectively. The average bleeding volume was 31.4mL and 28.6mL in the first and second group of animals respectively. The cutting time was normal and the bleeding was low during surgeries, except for one animal, where the cutting time was longer than usual, but the delay was not related to the device. The cutting effect of the tips on hard bone was good. No accidental damage was caused to nerves, vessels or soft tissues during surgeries. The bone cutting was performed from inside the spinal canal to the outside, which reduced the surgery risk significantly.

SEP latent period and fluctuation and MEP values were normal for all animals. This means that no damage was caused to animals' motor and sensory reflection during surgeries. Except for two

animals from the first group, who showed respectively an SEP with latent period longer than 10% for both sides before and after cutting, and an SEP fluctuation greater than 50% on the left sides after cutting, when compared to baseline values. These abnormal SEP values were probably related to the anesthesia as the animal returned to the normal state after completion of the surgery.

Clinical evaluation using the Tarlov rating standard process on day 1, day 3 and day 7 after surgery recorded a score of 4 for all animals, except for one animal who had a poor mental state during the first two days following surgery, but he returned to the normal state on the third day after surgery. No any other abnormal clinical symptoms were observed on the other animals.

CT scan performed on all animals on day 7 after surgery showed that the spine was in order and the curvature was normal. The posterior part of the vertebral plate of T11-T13 was missing, and an edema of soft tissue was observed. The soft tissue edema was a postoperative complication and wasn't caused by the tips themselves. The spinal cord near the spinal canal was not swelling, its density was normal and no obvious anomalies were seen in the spinal canal.

Histopathology examination performed on day 8 after surgery, showed no histopathological damage of the spinal cord tissue. Some inflammatory cells were observed in the specimens of the spinal cord membrane of 5 animals, and they were related to normal tissue reaction to surgery and not to the device.

7. Substantial Equivalence

Many of the features and technical characteristics of XD880A Ultrasonic Osteotomy Surgical System (subject device) are identical to those of the primary or secondary predicate devices (PD1 and PD2), and where there are differences, such differences do not have an impact on the safety or effectiveness of the subject device.

The differences are mainly in the dimensions of the systems components or number of operator-usable handpieces. Other differences, such as user interface design and minimum/maximum irrigation flow rates, provide more flexibility for users. Justification is provided in this submission for substantial equivalence for mentioned differences, including indications for use/intended use, and output power.

8. Conclusion

Based on the information contained within this submission, it is concluded that the **XD880A Ultrasonic Osteotomy Surgical System** is substantially equivalent to the identified predicate devices which are already in commercial distribution in the United States.