October 31, 2019

MediSonic Technology Co
% John Gillespy
FDA 510k Consultants, LLC
1100 Del Lago Cir #104
Palm Beach Gardens, Florida 33410

Re: K190281
Trade/Device Name: Ultrasonic Surgical System
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic Surgical Instrument and Accessories/Attachments
Regulatory Class: Class II
Product Code: JDX
Dated: February 4, 2019
Received: February 11, 2019

Dear John Gillespy:

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: 2019.10.31 13:24:47 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

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)*
K190281

Device Name
Ultrasonic Surgical System

Indications for Use *(Describe)*
Ultrasonic 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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Section 5 – 510(k) Summary (K190281)

1. 510(k) Submitter:
MediSonic Technology Co
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Las Vegas, NV 89141
Phone: 770-377-6365
Email: rbwilliams@medisonictech.com

2. Company Contact: Reginald Bart-Williams, CEO

3. Date of Submission: October 29, 2019

4. 510(k) Preparer:
John F. Gillespy, MBA
FDA 510k Consulting, LLC
Palm Beach Gardens, FL 33410
Phone: 386-243-4332
Email: john@fda510kconsultants.com

5. Device Classification:

Trade name:	Ultrasonic Surgical System
Common name:	Ultrasonic Surgical Bone Cutter, Ultrasonic Surgical Bone Drill
Device:	Instrument, Surgical, Sonic & Accessory
Class:	2
Regulation #:	888.4580
Product Code:	JDX

6. Predicate:

Applicant:	SMTP Technology Co, Ltd (China)
Device:	XD880A Ultrasonic Osteotomy Surgical System
510(k) Number:	K172464

7. Device Description… Ultrasonic 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 touch panel that allows the surgeon to control device operation. 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 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.

Ultrasonic 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 tip insert.

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

Ultrasonic Surgical System comes with separate handpieces for Ultrasonic Surgical Bone Cutting and Ultrasonic Surgical Bone Drilling.

The handpieces are reprocessed through cleaning and disinfection before each use. The ultrasonic tips, irrigation tubing, and water injection sleeves are provided sterile for single use.

8. Indications For Use… Ultrasonic 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.

   The device is intended for prescription use only.

9. Accessories and Components… The device comes with various ultrasonic cutting blades or "tips," water injection sleeves, and irrigation tubing, depending on the model and desired application. Other accessories include a foot switch (single or double), separate wrenches for handpiece and tips, and a user manual.

   Ultrasonic Tips – Each model (Bone Cutter and Bone Drill) offers three series of tips, 80mm Standard Length ("STD"), 140mm Extended Length ("EXT"), and 200mm or 330mm Minimally Invasive ("MINI"). The Bone Cutter provides five different tip shapes—tooth, toothless, hook, dome, and spoon, while the Bone Drill uses only the tooth-shaped blade. The Bone Cutter offers 14 STD, 11 EXT, and 6 MINI tips; meanwhile, the Bone Drill offers 5 STD, 4 EXT, and 4 MINI blades.

   Water Injection Sleeves – The Bone Cutter and Bone Drill offer 22 and 11 models of sleeves, respectively, for water injection during operation.

   Irrigation Tubing – The device comes with two irrigation tubes to remove fluid and debris from the surgical site.

10. Comparison To Predicate Device… See Table 5 on the following pages.

Table 5

Comparison Table

Characteristics	Subject Device	Predicate Device	Comparison
Name	Ultrasonic Surgical System	XD880A Ultrasonic Osteotomy Surgical System	NA
Manufacturer	MediSonic Technology Co (USA)	SMTP Technology Co, Ltd (China)	NA
510k Number	K190281	K172464	NA
Device Photo			NA
Class	II	II	Same
Regulation #	21 CFR 888.4580	21 CFR 888.4580	
Product Code	JDX	JDX	Same
Common Description	Sonic Surgical Instrument & Accessories/Attachments	Sonic Surgical Instrument & Accessories/Attachment	
Intended Use	Ultrasonic Surgery of Hard and Soft Tissue	Ultrasonic Surgery of Hard and Soft Tissue	Same
Indications For Use	An ultrasonic surgical system that includes a handpiece and associated cutting tips intended 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 (bone only), spine, and plastic/reconstructive surgery.	An ultrasonic surgical system that includes a handpiece and associated cutting tips intended 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 (bone only), spine, and plastic/reconstructive surgery	Same
Anatomical Site	Various hard & soft tissue locations	Various hard & soft tissue locations	Same

Physical Characteristics

System Design	Uses ultrasonic technology to generate mechanical micro-vibrations of tip insert connected to handpiece in conjunction with irrigation system and aspiration. Two handpieces.	Uses ultrasonic technology to generate mechanical micro-vibrations of tip insert connected to handpiece in conjunction with irrigation system. Single handpiece.	Handpieces differ for user preference
Energy Use	Transducer in handpiece converts electrical voltage supplied by ultrasonic generator in console into mechanical energy that induces vibration of tip insert at resonant frequency of tip insert.	Transducer in handpiece converts electrical voltage supplied by ultrasonic generator in console into mechanical energy that induces vibration of tip insert at resonant frequency of tip insert.	Same
Handpiece Tech	Piezoelectric	Piezoelectric	Same
Bone Cutting	Tips are used to fragment and reshape bone tissue through longitudinal vibration at high (low ultrasonic) frequency and small amplitude (less than 0.12mm), keeping soft tissues with elastic properties free of damage.	Tips are used to fragment and reshape bone tissue through longitudinal vibration at high (low ultrasonic) frequency and small amplitude (less than 0.12mm), keeping soft tissues with elastic properties free of damage.	Same
Bone Drilling	Same as above except uses both longitudinal & torsional vibration.	Same as above (longitudinal vibration only).	Torsional is common in ultrasonic bone drills (e.g., K010309)
Handpieces	Bone Cutter & Bone Drill models	Single straight model	Handpieces differ for user preference
Ultrasonic Freq	40 kHz	40 kHz	Same
Maximum Tip Amplitude	250 um +/- 20%	Not available	Not available
Operating Temp	55-95F (10-35C)	Not available	Not available
Relative Humidity	30-75% (non-condensing)	Not available	Not available
Material--Patient Contact	Tips - TC4 Titanium Alloy; Irrigation Sleeve - PTFE; Irrigation Tube - PVC	Tips - TC4 Titanium Alloy; Irrigation Sleeve & Tube - Medical Silicone Rubber	Tips same as P1; materials passed biocompatibility testing

Components

Console	Houses electronics, pumps, and mechanical parts. Includes touch screen to control system.	Houses electronics, pumps, and mechanical parts. Includes touch screen to control system.	Same
Handpiece	Handheld surgical device with tip that is applied to patient hard and soft tissue.	Handheld surgical device with tip that is applied to patient hard tissue.	Same
Footswitch	Connected to console; controls ultrasonic power and irrigation fluid.	Connected to console; controls ultrasonic power and irrigation fluid.	Same

Accessories

Tip	Range of tips	Range of tips	Same
Irrigation Set (Tubing & Surgical Tip Sleeve)	Provides user-supplied sterile irrigation fluid from IV set to peristaltic pump in console to distal end of surgical tip.	Provides user-supplied sterile irrigation fluid from IV set to peristaltic pump in console to distal end of surgical tip.	Same
Torque Wrench	To tighten or loosen tip	To tighten or loosen tip	Same

Bench Testing

Sterilization Validation	ISO 11135:2014	No mention in 510k Summary	Testing performed to current FDA-recognized standards
Package Integrity	ISO 11607:2006		
Shelf Life	ASTM F1980-16 (2 Years)		
Biocompatibility	ISO 10993-1:2008; ISO 10993-5:2009; ISO 10993-10:2010; ISO 10993-11:2017; ISO 10993-7:2008	Biocompatibility Testing	
Software	IEC 62304:2006	Software Testing	
Risk Management	EN ISO 14971:2012	ISO 14971 likely (in SW)	
Electrical Safety	IEC 60601-1:2005 +C1:2006+C2:2007+A1:2012	IEC 60601-1:2006	
EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2007/2010	
Usability	IEC 62366-1:2015	Not provided	
Mechanical Safety	IEC 61847:1998	Mechanical & Acoustic (standard not provided)	

All components of Ultrasonic Surgical System were included in bench testing, which included sterilization validation, biocompatibility, software verification and validation, EMC and electrical safety, usability, and mechanical safety.

11. Performance Testing… Ultrasonic Surgical System was subjected to the following non-clinical bench tests. All testing standards are currently FDA recognized, and the device passed each test:

    - EMC – IEC 60601-1-2 Edition 4:2014… Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests

    - Electrical Safety – IEC 60601-1:2015, Mod… Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance

    - Biocompatibility – ISO 10993-1:2009… Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

    - Biocompatibility – ISO 10993-5:2009… Biological evaluation of medical devices - Part 5: Test methods to assess the in vitro cytotoxicity of medical devices

    - Biocompatibility – ISO 10993-10:2009… Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

    - Biocompatibility – ISO 10993-7:2008… Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

    - Biocompatibility – ISO 10993-11:2017… Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

    - Sterilization Validation – ISO 11135:2007 (1st Edition)… Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

    - Sterilization Packaging – ISO 11607-1:2006… Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems

    - Packaging Validation – ISO 11607-2:2006… Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

    - Shelf Life – ASTM F1980-16… Standard guide for accelerated aging of sterile barrier systems for medical devices

    - Usability Engineering – IEC 62366-1:2015… Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

    - Ultrasonic Surgical Systems – IEC 61847:1998… Ultrasonics – Surgical Systems – Basic Output Characteristics

- Software Life Cycle – IEC 62304:2006… Medical Device Software – Software Life Cycle Processes
- Risk Management – ISO 14971:2007… Medical Device – Application of Risk Management to Medical Devices

12. Patient-Contacting Materials… Ultrasonic Surgical System components that come into direct contact with patients during surgical procedures include the ultrasonic surgical tips. According to ISO 10993-1, these components are classified as "external communicating devices," as they get in contact with "tissue/bone" for a duration less than 24 hours. The cutting tips are made of Titanium Alloy TC4.

    The other system components that can have indirect contact with the surface of patient's body during surgery are water injection sleeves and irrigation tubing, and the duration of their contact is also less than 24 hours. The sleeves and tubing are made of PTFE and PVC, respectively.

    As shown in "Performance Testing" above, biocompatibility studies have been conducted on the tips, sleeves, and tubing, and test results showed that all materials are biocompatible.

13. Software Verification and Validation… 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" (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.

14. Substantial Equivalence… Many of the features and technical characteristics of Ultrasonic Surgical System (subject device) are identical to those of the predicate device, and where there are differences, such differences do not have an impact on the safety or effectiveness of the subject device.

    Ultrasonic Surgical System successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (2014). The steps are summarized below:

    - The predicate is legally marketed and was found substantially equivalent through 510(k) premarket submission.
    - The subject and predicate device have the same intended use.
    - Technological differences between the subject and predicate were evaluated; none of the differences raised different issues of safety and effectiveness.
    - The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—electrical safety, EMC, biocompatibility, sterilization validation, package integrity, shelf life, usability

engineering, and ultrasonic surgical systems performance testing. All tests were conducted to FDA-recognized standards.

- Data from these tests demonstrated equivalence and support the indications for use.

In conclusion, all necessary testing has been performed and the results support the conclusion that Ultrasonic Surgical System is substantially equivalent to the legally marketed predicate based on both (a) comparison of intended use, materials, technology, and design and (b) testing to FDA-recognized standards, and the device thus does not raise any concerns of safety or effectiveness.

Based on the information contained within this submission, it is concluded that Ultrasonic Surgical System is substantially equivalent to the identified predicate device and warrants clearance for marketing activities.