DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 25, 2016

Mectron Spa
% Roger Gray
VP, Quality And Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153 IT

Re: K153743
Trade/Device Name: Piezosurgery Plus
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic Surgical Instrument And Accessories/Attachments
Regulatory Class: Class II
Product Code: JDX, DZI, ERL, HBE, HWE
Dated: April 21, 2016
Received: April 25, 2016

Dear Mr. Gray:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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

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)*
K153743

Device Name

PIEZOSURGERY PLUS

Indications for Use *(Describe)*

The Piezosurgery® Plus is an ultrasonic surgical system consisting of handpieces and associated tips for 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, and
- Orthopedic surgery.

The device may also be used with endoscopic visual assistance to perform the above listed procedures.

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:	December 22, 2015
510(k) Submitter:	MECTRON S.p.a Via Loreto 15 16042 Carasco - (GE) - ITALY Phone: +39 0185 35 361 Fax: +39 0185 351 374
510(k) Contact Person:	Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10 00153 Rome, Italy Phone: +39 06 578 2665 Fax: +39 06 574 3786 email: rgray@donawa.com
Manufacturer:	MECTRON S.p.a Via Loreto 15 16042 Carasco - (GE) - ITALY Establishment Registration Number: 3003933619

2. DEVICE

Proprietary Name:	Piezosurgery Plus
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 vibrates at high frequencies, and 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. IDENTIFICATION OF PREDICATE DEVICES

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

Table 1: Identification of 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
Alliger Ultrasonic Surgical System Model AUSS-7	MISONIX INC	LFL	K070313	11 May 2007

4. DEVICE DESCRIPTION AND TECHNOLOGICAL CHARACTERISTICS

The Piezosurgery Plus device is a surgical system that uses ultrasonic energy to generate mechanical micro-vibration of associated inserts, to perform cutting of bony structures in the procedures defined by its intended use.

The Piezosurgery Plus system consists of a control unit which provides control and power functions, two different detachable surgical handpieces which provide the ultrasonic mechanical energy, two peristaltic irrigation pumps, two irrigation tubing systems, a range of single use insert tips, torque wrenches, and a foot-pedal.

The control unit has a color LCD touch screen user interface for the selection/visualization of device functional parameters. Inside the control unit are located two ultrasonic generators which drive the two handpieces, the electrical power supply modules and the microprocessor electronic board that controls and supervises the functional parameters of the device.

The two piezoelectric ultrasonic handpieces available for the Piezosurgery Plus are identified as ‘Piezosurgery Medical’ and ‘Piezosurgery Medical +’. The handpieces are reusable and capable of being reprocessed by autoclaving.

The handpiece labeled ‘Piezosurgery Medical +’, uses identical technology to the ‘Piezosurgery Medical’ handpiece but differs from it as it contains larger piezoceramic rings in its transducer, allowing more efficient cutting of thick bony structures, and also use with inserts with extended reach for minimally invasive bone surgery in long narrow access path, in small cavities and other hard to reach areas.

The two peristaltic pumps, which provide, through the two single-use irrigation tubing sets, sterile fluid to the surgical site, are mounted on the two lateral panels of the control unit.

The control unit includes connectors for the handpieces and for the foot-pedal. Each handpiece receives the functional drive signals from the control unit.

Each irrigation tubing set connects each handpiece irrigation connector to a sterile fluid bag (not supplied with the device) via the associated peristaltic pump.

The user may select either of the two handpieces for activation by selection from the LCD touch-screen. Ultrasonic power and irrigation flow are simultaneously activated for the selected handpiece by pressing the foot-pedal.

The ultrasonic generator(s) provides electrical energy at a specific range of frequency. The generator must drive the transducer at or near its anti-resonance frequency for optimal operation. A key function of the generator is to locate the anti-resonant frequency and drive the output at this frequency.

In particular, the generator conducts an automatic frequency sweep across a frequency interval of 36 kHz - 24 kHz to locate and lock the electrical resonance frequency of the transducer/insert system. The functional ultrasonic frequency of the device is between approximately 24 and 36 kHz. The Piezosurgery

Plus handpieces transducers and family of inserts are designed to resonate in this range of frequencies.

The ultrasonic signal can be modulated in amplitude, generating a sinusoidal signal with alternative amplitudes of high and low value that creates a hammer effect that enhances cutting and minimizes insert stalling.

The Piezosurgery Plus complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC 60601-1 and IEC 60601-1-2.

5. INTENDED USE/INDICATIONS FOR USE

The Piezosurgery® Plus is an ultrasonic surgical system consisting of handpieces and associated tips for 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, and
- Orthopedic surgery

The device may also be used with endoscopic visual assistance to perform the above listed procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Piezoelectric ultrasonic technology is used by the subject device and both the predicate devices to generate mechanical micro-vibrations of the insert connected to the handpiece. The subject device and predicate devices share many technological characteristics, as identified in the following section.

7. SUBSTANTIAL EQUIVALENCE

A comparison of the subject device with the predicate devices is shown in Table 2.

Table 2: Substantial Equivalence Comparison between Piezosurgery Plus and the Predicate Devices

Feature	Piezosurgery Plus Subject Device	Piezosurgery Flex Primary Predicate Device (PD1)	Alliger Ultrasonic Surgical System Model AUSS-7 Secondary Predicate Device (PD2)	Equivalence
Manufacturer	MECTRON SPA Via Loreto 15 16042 Carasco Italy	MECTRON SPA Via Loreto 15 16042 Carasco ITALY	MISONIX INC. 1938 New Highway Farmingdale, NY 11736 USA	N/A
510(k) Number	Subject of this submission	K132848	K070313	N/A
Regulation Number	888.4580	888.4580	Unclassified	Identical to PD1
Regulation Name	Sonic surgical instrument and accessories/attachments	Sonic surgical instrument and accessories/attachments	Instrument, Ultrasonic Surgical	Identical to PD1
Common/Usual Name	Bone cutting instruments and accessories	Bone cutting instruments and accessories	Ultrasonic Surgical System Ultrasonic Surgical Aspirator	Identical to PD1
Regulation Panel	Orthopedic	Orthopedic	General & Plastic Surgery	Identical to PD1
Product Code	JDX, DZI, ERL, HBE, HWE	JDX, DZI, ERL, HBE, HWE	LFL	Identical to PD1
Regulatory Class	Class II	Class II	Unclassified	Identical to PD1

Table 2: Substantial Equivalence Comparison between Piezosurgery Plus and the Predicate Devices

Feature	Piezosurgery Plus Subject Device	Piezosurgery Flex Primary Predicate Device (PD1)	Alliger Ultrasonic Surgical System Model AUSS-7 Secondary Predicate Device (PD2)	Equivalence
Intended Use / Indications for Use	The Piezosurgery® Plus is an ultrasonic surgical system consisting of handpieces and associated tips for 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, and • Orthopedic surgery The device may also be used with endoscopic visual assistance to perform the above listed procedures.	The PIEZOSURGERY FLEX is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone, osteotomy, osteoplasty, and drilling in a variety of surgical procedures, including but not limited to: • Otolaryngological, • Oral/maxillofacial, • Hand and Foot, • Neurosurgical, • Spine, • Plastic reconstructive surgery. It may also be used with endoscopic visual assistance to perform the above listed procedures.	The AUSS-7 ULTRASONIC SURGICAL SYSTEM is indicated for use in the fragmentation and aspiration of both soft and hard (e.g. bone) tissue in the following surgical specialties: • Neurosurgery • Gastrointestinal and affiliated organ surgery • Urological surgery • Orthopedic surgery • Gynecology • Thoracic surgery • Wound care	Substantially equivalent
Technological characteristics (mechanism of action)	Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips.	Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips.	Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips.	Identical to PD1 & PD2
Transducer Technological characteristics	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks that convert the electrical input signal from the generator to ultrasonic vibration of the insert	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks that convert the electrical input signal from the generator to ultrasonic vibration of the insert	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks that convert the electrical input signal from the generator to ultrasonic vibration of the insert	Identical to PD1 & PD2
Operating frequency range	24 kHz to ~ 36 kHz	24 kHz to ~ 36 kHz	22.5 kHz	Identical to PD1
Electrical power input	100 - 240 VAC - 50/60 Hz.	100 - 240 VAC - 50/60 Hz.	120 VAC - 60 Hz	Identical to PD1
Output power	Two handpieces: Approximately: 24 W Approximately: 75 W	One handpiece: Approximately 24 W	One handpiece: 130 Watt (max.)	See note **SE#2**
Device type	Table top device	Table top device	Table top device	Identical to PD1 & PD2
User Interface	The functional parameters are displayed and controlled through a 12.1 inch LCD Color Touch Screen.	The functional parameters are displayed and controlled through a console with touch panel	The functional parameters are displayed on a color LCD Screen on the device console	Substantially equivalent
Operation	The device has two separate piezoelectric ultrasonic handpieces: the operator may choose either of the two handpieces by selection from the LCD touch-screen.	The device has one piezoelectric ultrasonic handpiece.	The device has one piezoelectric ultrasonic handpiece.	Substantially equivalent
Ultrasonic vibration activation	Foot-pedal connected to the device control unit by means of a cord.	Foot-pedal connected to the device control unit by means of a cord.	Foot-pedal connected to the device control unit by means of a cord.	Identical to PD1 & PD2
Automatic resonance frequency tuning	Electronics with automatic tuning of the resonance frequency	Electronics with automatic tuning of the resonance frequency.	Unknown.	Identical to PD1
Modulated ultrasonic signal mode	Yes	Yes	Unknown	Identical to PD1

Table 2: Substantial Equivalence Comparison between Piezosurgery Plus and the Predicate Devices

Feature	Piezosurgery Plus Subject Device	Piezosurgery Flex Primary Predicate Device (PD1)	Alliger Ultrasonic Surgical System Model AUSS-7 Secondary Predicate Device (PD2)	Equivalence
Irrigation system	External irrigation tubing connecting the handpiece to the irrigation bag via a peristaltic pump.	External irrigation tubing connecting the handpiece to the irrigation bag via a peristaltic pump.	External irrigation tubing connecting the handpiece to the irrigation bag via a peristaltic pump.	Identical to PD1 & PD2
Irrigation flow rate adjustment	Flow rate adjustable through the LCD touch screen of the control unit. Flow rate adjustable from 4 ml/min to approx. 81 ml/min.	Flow rate adjustable through the touch panel of the control unit. Flow rate adjustable from 8 ml/min to approx. 65 ml/min	Flow rate adjustable through the front panel of the control unit. Max flow approx 67 ml/min	Substantially equivalent
Irrigant fluid	Physiological sterile saline solution or sterile water	Physiological sterile saline solution or sterile water	Physiological sterile saline solution.	Identical to PD1 & PD2
Electrical safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Complies with IEC 60601-1	Identical to PD1 & PD2
Electromagnetic Compatibility	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Identical to PD1 & PD2
Device contains software?	Yes	Yes	Yes	Identical to PD1 & PD2
Software Validation	In accordance with FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"	In accordance with FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"	Unknown	Identical to PD1
Parts supplied sterile	Yes: Irrigation tube set and the insert tips/extensions/ protective sleeves are supplied sterile for single use only.	Yes: Irrigation tube set and the insert tips are supplied sterile for single use only.	Yes: Irrigation tube set and the insert tips are supplied sterile for single use only.	Identical to PD1 & PD2
Sterilization method	Ethylene Oxide (EtO) Sterilization Process	Ethylene Oxide (EtO) Sterilization Process	Unknown	Identical to PD1
Parts need to be sterilized	Yes: Ultrasonic handpieces, torque wrenches and other minor accessories are reusable and must be sterilized prior to reuse.	Yes: Ultrasonic handpiece, torque wrench and other minor accessories are reusable and must be sterilized prior to reuse.	Yes Ultrasonic handpiece, torque wrench and other minor accessories are reusable and must be sterilized prior to reuse.	Identical to PD1 & PD2
Recommended sterilization method	Steam Sterilization (Pre-vacuum) Sterilization Temperature:132°C (270°F). Minimum Exposure Time: 4 min.	Steam Sterilization (Pre-vacuum) Sterilization Temperature:132°C (270°F). Minimum Exposure Time: 4 min.	Steam Sterilization (Pre-vacuum) Sterilization Temperature:132°C (270°F). Minimum Exposure Time: 4 min.	Identical to PD1 & PD2
Sterility Assurance Level	SAL = 10^{-6}	SAL = 10^{-6}	SAL = 10^{-6}	Identical to PD1 & PD2
Tip Inserts that come into direct contact with patients	Raw Material: Stainless steel. The insert tips are secured to the handpiece by a thread, using a torque wrench.	Raw Material: Stainless steel. The insert tips are secured to the handpiece by a thread, using a torque wrench.	Information not available. The insert tips are secured to the handpiece by a thread, using a torque wrench	Identical to PD1
Control unit dimensions	Width: 410 mm Height: 310 mm Depth: 380mm	Width: 300 mm Height: 95 mm Depth: 250mm	Width: 410 mm Height: 180 mm Depth: 485mm	Differences have no impact on safety and effectiveness

Many of the features and characteristics of the subject device are identical to those of the primary predicate device (PD1), and where there are differences, the subject device is substantially equivalent to the secondary predicate device (PD2).

Some differences clearly have no impact on safety or effectiveness, such as dimensional differences, and the number of operator-usable handpieces, while other differences, such as user interface design and

minimum/maximum irrigation flow rates, provide for improved flexibility of use. Justification is provided in this submission for substantial equivalence for more significant differences, including indications for use/intended use, and output power.

8. PERFORMANCE TESTING

Electrical safety and electromagnetic compatibility: The subject device was tested to confirm compliance of the subject device to IEC 60601-1:2005 + AMD1:2012 and IEC 60601-1-2:2007**.**

Software verification and validation: Software verification and validation testing were conducted and documentation was provided as recommended by 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 'major' level of concern.

Biocompatibility: The Piezosurgery Plus components that come into direct contact with patients during surgical procedures are the tip inserts, which are supplied for single use only. According to ISO 10993-1, these components are classified as 'external communicating devices', in contact with 'tissue/bone/dentin' with 'limited' contact duration ≤ 24 h.

The materials with which the Piezosurgery Plus insert tips are manufactured are identical to the insert tip materials cleared with the predicate device Piezosurgery Flex (K132848). Materials not used in this predicate device are titanium alloy and stainless steel AISI 316/316L, which are in accordance with relevant standards for surgical use, and PEEK, for which biocompatibility data is provided.

Mechanical testing: Three types of mechanical performance tests have been carried out:

Test type 1: Osteotomy/osteoplasty comparative test. The objective of these tests was to provide evidence that the subject device tip inserts are able to efficiently carry out the surgical procedures of osteoplasty and osteotomy with results at least equivalent to the identified predicate device with equivalent inserts.

The tests were conducted using cow femur or rib samples. Osteotomy efficiency was evaluated by measuring the cutting speed of the insert. Osteoplasty efficiency was evaluated by measuring the volume of bone removed. The test results demonstrate the subject device osteotomy/osteoplasty tip inserts are able to carry out osteoplasty and osteotomy in a manner at least equivalent to the applicable predicate device/tip combination, without raising any new questions of safety and effectiveness.

Test type 2: Bone safety. The objective of this test was to demonstrate the ability of the subject device to cut/remove bone without causing bone necrosis. To evaluate the presence of necrosis, pictures of the bone surfaces derived from the above test type 1 were taken using a Veho Discovery USB microscope at 40x magnification. No evidence of bone necrosis was recorded on any bone sample obtained by using 'worst case' tip inserts.

Test type 3: Device safety. The object of this test was to demonstrate the bone cutting ability of the subject inserts without insert breakage. To carry out this test, the 'worst case' inserts were subjected to stress tests, being subjected to a number of mechanical stress cycles (600 working cycles), to simulate clinical usage. Five samples were tested for each investigated insert type. No insert breakages were noted during these tests.

No animal or clinical performance tests have been carried out.

9. CONCLUSION

Based on the information contained within this submission, it is concluded that the Mectron Piezosurgery Plus is substantially equivalent to the identified predicate devices which are already in commercial distribution in the United States.