DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2017

SATELEC
% Ms. Argie Zoubroulis
Quality Manager
ACTEON, Inc.
124 Gaither Drive, Suite #140
Mt. Laurel, New Jersey 08054

Re: K163610
Trade/Device Name: PIEZOTOME M+, PIEZOTOME M+ Handpiece
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic Surgical Instrument and Accessories/Attachments
Regulatory Class: Class II
Product Code: JDX, HWE, DZI, ERL, HBE
Dated: April 19, 2017
Received: April 21, 2017

Dear Ms. Zoubroulis:

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,

Jennifer R. Stevenson -S

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)*
K163610

Device Name
PIEZOTOME M+

Indications for Use *(Describe)*
Piezotome® M+ is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical spine, and plastic/reconstructive surgery.
Piezotome® M+ is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral 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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006 – 510(k) Summary (SMDA Requirements)

Additional Information – February 17, 2017

Summary of Safety And Effectiveness
[As Required by 21 CFR 807.92.c]

I – SUBMITTER

01.a. 510(k) Submitter:

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01.b. Contact Person:

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01.c. Establishment Registration Number:	8044015
01.d. Date Prepared:	November 29, 2016
01.e. Type of 510(k) submission:	Traditional 510(k) Submission.

II – DEVICE

02.a. Trade Name of Device:	PIEZOTOME M+
02.b. Common Name of Device:	Sonic surgical instrument and accessories / attachments
02.c. Classification Regulation:	21 CFR 888.4580
02.d. 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
02.e. Medical Device Class:	II
02.f. Panel:	Orthopedic

006 – 510(k) Summary (SMDA Requirements)

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02.g. Product Code: JDX

02-h. Subsequent Product Codes: HWE, DZI, ERL, HBE

III – PREDICATE DEVICES

The Substantial Equivalence (SE) of PIEZOTOME M+ is based on the Predicate Devices identified in the Table 01.

Table 01 – Identification of Legally Marketed Predicate Devices

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
Piezoelectric System	SATELEC	JDX, DZI, ERL, HBE, HWE	K100410	April 28, 2010
PIEZOTOME 2	SATELEC	DZI	K091331	Dec 11, 2009

SATELEC Piezoelectric System Predicate Device has not been subject to a design-related recall.
SATELEC PIEZOTOME 2 Predicate Device has not been subject to a design-related recall.

IV – DEVICE DESCRIPTION

PIEZOTOME M+ is an Electromedical Device that uses micro-vibrations of associated Tips, to perform the clinical procedures defined in Intended Use.

PIEZOTOME M+ consists of a Console, a Multifunction footswitch, two reusable Handpieces, a range of Dental Tips, a range of Bone Surgery Tips, two Irrigation Pumps with Irrigation tubings and Flat Wrenches for Tips,

The Console is the heart of the PIEZOTOME M+. The Console contains the display board and the motherboard. Ultrasonic Handpieces and Footswitch are connected to the Console. The LCD Color Touch screen present on the front panel is used to define the settings of the PIEZOTOME M+ (modes, ultrasonic power, irrigation flow values)

The Multifunction footswitch has different functions. The access to a number of functions on the control footswitch allows the practitioner to work in a perfectly sterile environment, avoiding the risk of cross-contamination. The Footswitch is classified IP X8 (Protective Index) for operating theater applications.

The Ultrasonic Handpieces are held in the Surgeron's hand. The Ultrasonic Handpieces are connected to the Console via a Handpiece Cord. A Handpiece is dedicated to Conventional dental procedures (NEWTRON LED Handpiece) and a Handpiece is dedicated to Bone Surgery procedures (PIEZOTOME M+ Handpiece). The Ultrasonic Handpieces are equipped with a Piezoelectric Transducer. The Piezoelectric transducer converts the Electrical Signal delivered by the Console into mechanical micro-vibrations. The Ultrasonic Handpieces are reusable and Sterilizable by autoclaving.

The Pump housings are designed to accommodate Irrigation Tubing cassettes. Irrigation Tubings are Single Use and delivered under Sterile State. Irrigation Solution is intended to cool the clinical site and eliminate by rinsing the fragments such as bone or teeth.

Tips are fixed by means of a Wrench at the extremity of the Ultrasonic Handpieces. Tips are in direct contact to the patient. The ultrasonic mechanical vibrations transmitted to the Tip permits the realization of the clinical procedures defined in Intended Use. Bone Surgery Tips are Single Use and delivered under Sterile State. Dental Tips are reusable.

006 – 510(k) Summary (SMDA Requirements)

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V – INDICATION FOR USE

Piezotome® M+ is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical spine, and plastic/reconstructive surgery.
Piezotome® M+ is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.

VI – COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES (SUBSTANTIAL EQUIVALENCE)

A comparison Between PIEZOTOME M+ et The Predicate Devices is present in Table 02.

Table 02 – Comparison Between PIEZOTOME M+ et the Predicate Devices

	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
Intended Use	Piezotome® M+ is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical spine, and plastic/reconstructive surgery. Piezotome® M+ is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics,	The Piezoelectric System, distributed by Synthes, is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical spine, and plastic/reconstructive surgery.	The intended use of the SATELEC PIEZOTOME 2 is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental	Substantially equivalent to PD#1 for Bone Surgery clinical application – No impact. Substantially equivalent to PD#2 for Dental clinical application – No impact

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	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
	endodontics, scaling, prosthesis and oral surgery.		practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.	
Code Product	JDX	JDX	DZI	Identical to PD#1
Subsequent product Codes	DZI, ERL, HBE, HWE	DZI, ERL, HBE, HWE	/	Identical to PD#1
Part	888 – Orthopedic Device	888 – Orthopedic Device	872 - Dental devices	Identical to PD#1
Regulation Number	21 CFR 888.4580	21 CFR 888.4580	21 CFR 872.4120	Identical to PD#1
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	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	A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw	Identical to PD#1
Regulation Name	Sonic surgical instrument and accessories / attachments	Sonic surgical instrument and accessories / attachments	Bone Cutting Instrument and Accessories	Identical to PD#1
Regulatory Class	II	II	II	Identical to PD#1 and PD#2
Principle of operation				
Principle	An electrical signal emitted by the medical device is supplied to the dental piezo-ultrasonic Handpiece. It comprises a piezoelectric ceramic transducer, which converts the electrical signal into ultrasonic vibrations. Mechanical vibrations are transmitted to a tip attached to the end of the ultrasonic Handpiece			Identical to PD#1 and PD#2
Dimensions of the Console				
Height / Depth / Widh (mm)	149.5 / 339.9 / 472.9	149.5 / 339.9 / 472.9	149.5 / 339.9 / 472.9	Identical to PD#1 and PD#2
Power Supply				
Supply Voltage (VAC)	100 to 230	100 to 230	100 to 230	Identical to PD#1 and PD#2
Frequency (Hz)	50 to 60	50 to 60	50 to 60	Identical to PD#1 and PD#2
Power Consumption (VA)	150	150	150	Identical to PD#1 and PD#2

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	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
Electrical Safety Classification				
Equipment Classification	Class 1	Class 1	Class 1	Identical to PD#1 and PD#2
Electrical Type	BF Type	BF Type	BF Type	Identical to PD#1 and PD#2
Additional earth	Equipotential plug	Equipotential plug	Equipotential plug	Identical to PD#1 and PD#2
Applied Parts on the Console				
Quantity of connectors for Applied Parts	2	2	2	Identical to PD#1 and PD#2
Localization	Right and left of the front panel	Right and left of the front panel	Right and left of the front panel	Identical to PD#1 and PD#2
Internal constitution of the Console				
Power supply	Power Switching Supply (PSU)	Power Switching Supply (PSU)	Power Switching Supply (PSU)	Identical to PD#1 and PD#2
Mother Board	Same Mother board	Same Mother board	Same Mother board	Identical to PD#1 and PD#2
Display Board	Same Display Board	Same Display Board	Same Display Board	Identical to PD#1 and PD#2
Display Board and Mother Board Fire aspects	UL94 Printed Circuit Board	UL94 Printed Circuit Board	UL94 Printed Circuit Board	Identical to PD#1 and PD#2
Software Constitution				
Mother Board Software	BO209034	BO209034	BO209034	Identical to PD#1 and PD#2
Display Board Software	BO209284	BO209274	BO209284	Identical to PD#2
External constitution of the Console				
Fire aspects (for Casing)	UL 94 V0 Thermoplastic Material	UL 94 V0 Thermoplastic Material	UL 94 V0 Thermoplastic Material	Identical to PD#1 and PD#2
Pictures				Difference of colors – Identical Shape – No Impact
Piezoelectric Performances for Bone Surgery				
Output Ultrasonic frequency	Min 28 kHz	Min 28 kHz	Min 28 kHz	Identical to PD#1 and PD#2
Maximum Handpiece current range	270 mA	270 mA	270 mA	Identical to PD#1 and PD#2
Available modes	D1, D2, D3, D4	D1, D2, D3, D4	D1, D2, D3, D4	Identical to PD#1 and PD#2
Frequency Modulation for D1, D2, D3	60 Hz	60 Hz	60 Hz	Identical to PD#1 and PD#2
Frequency Modulation for D4	30 Hz	30 Hz	30 Hz	Identical to PD#1 and PD#2
Piezoelectric Performances for Dental Application				
Output Ultrasonic frequency	Min 28 kHz	-	Min 28 kHz	Identical to PD#2

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	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
Maximum Handpiece current range	100 mA	-	100 mA	Identical to PD#2
Available modes	SOFT / MEDIUM / HIGH / BOOST	-	SOFT / MEDIUM / HIGH / BOOST	Identical to PD#2
Irrigation Performances				
Irrigation Pumps	2	2	2	Identical to PD#1 and PD#2
Minimum Irrigation Flow Rate (nominal)	10 ml/min	10 ml/min	10 ml/min	Identical to PD#1 and PD#2
Maximum Irrigation Flow Rate (nominal)	120 ml/min	120 ml/min	120 ml/min	Identical to PD#1 and PD#2
User Interface for setting				
User interface for Setting	5.1” color touch screen LCD on front panel	5.1” color touch screen LCD on front panel	5.1” color touch screen LCD on front panel	Identical to PD#1 and PD#2
Ultrasonic Power Setting	Accessible on 5.1” color touch screen LCD on front panel	Accessible on 5.1” color touch screen LCD on front panel	Accessible on 5.1” color touch screen LCD on front panel	Identical to PD#1 and PD#2
Irrigation Flow Setting	Accessible on 5.1” color touch screen LCD on front panel	Accessible on 5.1” color touch screen LCD on front panel	Accessible on 5.1” color touch screen LCD on front panel	Identical to PD#1 and PD#2
Footswitch				
Type of Footswitch	Multifunction	Multifunction	Multifunction	Identical to PD#1 and PD#2
Number of actuators on Footswitch	3	5	5	No impact
Environmental				
Where used	Operating Theatre	Operating Theatre	Dental office	Identical to PD#1
Operating Temperature	+10°C to +30°C	+10°C to +30°C	+10°C to +40°C	Identical to PD#1
Storage Temperature	0°C to +50°C	-20°C to +70°C	-20°C to +70°C	No impact
Anatomical site	General Oral Sphere	General	Oral sphere	Substantially equivalent to PD#2 for Dental clinical application – No impact Substantially equivalent to PD#1 for Bone Surgery clinical application – No impact.
Handpieces				
Bone Surgery Handpiece	PIEZOTOME M+ Handpiece (grey color)	Piezoelectric Handpiece (black color)	PIEZOTOME Handpiece (grey color)	Substantially Equivalent - No Impact
Dental Handpiece	NEWTRON Handpiece	-	NEWTRON Handpiece	Identical to PD#2
Type of Applied Part	Ultrasonic Handpiece	Ultrasonic Handpiece	Ultrasonic Handpiece	Identical to PD#1 and PD#2

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	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
Technology used for Handpieces	Piezoelectric technology	Piezoelectric technology	Piezoelectric technology	Identical to PD#1 and PD#2
Dimensions of the Bone Surgery Handpieces				
Length (mm)	130	130	130	Identical to PD#1 and PD#2
Maximum Diameter (mm)	23	23	23	Identical to PD#1 and PD#2
Dimensions of the Dental Handpieces				
Length (mm)	112	-	112	Identical to PD#2
Maximum Diameter (mm)	21	-	21	Identical to PD#2
Irrigation Tubing				
Length (mm)	3550	3550	2550	Identical to PD#1
Principle of irrigation	Peristaltic tape	Peristaltic tape	Peristaltic tape	Identical to PD#1 and PD#2
Dimensions of the Footswitch				
Width / Height / Depth (mm)	311 / 181 / 209	311 / 181 / 209	311 / 181 / 209	Identical to PD#1 and PD#2
Bone Ultrasonic Tips				
Tips dedicated for Osteotomy, osteoplasty, shaping, and smoothing of bones and teeth	BS1L	Saw 20.1 x 21.4 x 4.0 x 0.6 mm - 03.000.402S	-	Substantially Equivalent - No Impact
	BS4	Scalpel Rnd 22.45 x 12.6 x 3.9 mm dia x 0.7 mm - 03.000.405S	-	
	SL1	Diamond 24.6 x 12.85 x 2.6 x 0.6 mm - 03.000.409S	-	
	SL2	Diamond Rnd 21.9 x 12.4 x 1.8 mm - 03.000.410S	-	
	BS1 XXL	Saw Slim 104 mm - 03.000.412S	-	
	BS2L XL	Saw L Long - 03.000.418S	-	
	BS2R XL	Saw R Long - 03.000.419S	-	
	BS6 XXL	Scalpel Flat 15° 129 mm - 03.000.421S - 03.000.411S	-	
	BS1 RD	Saw 20 mm - 03.000.424S	-	
Tips dedicated for Decorticating	SL3	Sinus Lift 22.9 x 10.1 x 5 dia x 0.4 mm - 03.000.411S	-	
Cleaning, Disinfection				
Dental Ultrasonic Tips	Re-usable, Cleanable, Disinfectable	-	Re-usable, Cleanable, Disinfectable	Identical to PD#2

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	New Device	Predicate Device #1 (PD#1)	Predicate Device #2 (PD#2)	Equivalence
Trade / Device Name	PIEZOTOME M+	Piezoelectric System	PIEZOTOME 2	
Knumber	Unknown	K100410	K091331	
Bone Ultrasonic Tips	Single Use	Single Use	Re-usable, Cleanable, Disinfectable	Identical to PD#1
Dental Ultrasonic Handpiece	Re-usable, Cleanable, Disinfectable	-	Re-usable, Cleanable, Disinfectable	Identical to PD#2
Bone Ultrasonic Handpiece	Re-usable, Cleanable, Disinfectable	Re-usable, Cleanable, Disinfectable,	Re-usable, Cleanable, Disinfectable	Identical to PD#1 and PD#2
Sterilization / Sterile State				
Dental Ultrasonic Tips	Sterilizable 132°C / 4 min - Re-usable	-	Sterilizable 132°C / 4 min - Re-usable	Identical to PD#2
Bone Ultrasonic Tips	Provided under Sterile State Single Use	Provided under Sterile State Single Use	Sterilizable 132°C / 4 min Re-usable	Identical to PD#1
Dental Ultrasonic Handpiece	Sterilizable 132°C / 4 min	-	Sterilizable 132°C / 4 min	Identical to PD#1
Bone Ultrasonic Handpiece	Sterilizable 132°C / 4 min	Sterilizable 132°C / 4 min	Sterilizable 132°C / 4 min	Identical to PD#1 and PD#2
Irrigation Tubing	Provided under Sterile State - Single Use	Provided under Sterile State - Single Use	Provided under Sterile State Single Use	Identical to PD#1 and PD#2
Biocompatibility				
Tip material in contact to the Patient	Stainless Steel or Medical Material used in Medical Application	Stainless Steel or Medical Material used in Medical Application	Stainless Steel or Medical Material used in Medical Application	Identical to PD#1 and PD#2
Ultrasonic Handpiece material in contact to Patient	Polyphenylsulfone (PPSU) used in Medical Application	Polyphenylsulfone (PPSU) used in Medical Application	Polyphenylsulfone (PPSU) used in Medical Application	Identical to PD#1 and PD#2
Safety / EMC and Additional Safety Mark for USA and CANADA				
Safety and EMC Standard	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Identical to PD#1 and PD#2
US Electrical Standard	ANSI/AAMI ES 60601-1: 2005/(R)2012	UL 60601-1: 2003	-	No impact

A lot of features and characteristics of PIEZOTOME M+ are identical to the Predicate Device #1 and Predicate Device #2. The Identified differences have no impact on the Substantial Equivalence.

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VII – PERFORMANCE DATA

Electromagnetic Compatibility Test: The Electromagnetic Compatibility Tests have been performed according to IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). (Recognition Number 5-64).

Electrical Safety Tests: The Electrical Safety Tests have been performed according to IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (General). (Recognition Number 5-71) included USA and Canadian Deviations.

Additional Safety Mark: PIEZOTOME M+ is in accordance with ANSI / AAMI ES 60601-1: 2005 / (R) 2012 and bears the *c BVS **us marking, related to the file number GSAA.

Software Verification and Validation: Software Verification and Validation activities were conducted and documented according to the document named "*Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" dated May 11, 2005. Moreover, the Software System included in PIEZOTOME M+ is strictly the same Software as the Predicate Device PIEZOTOME 2 (K091331, cleared December 11, 2009).

Performance Testing bench: The comparison of performances between PIEZOTOME M+ and Predicate Devices has been performed.
The Technical Characteristics for Bone Surgery Application of PIEZOTOME M+ (Piezoelectric Performances and Irrigation Performances) are similar as the Predicate Devices Piezoelectric System (K100410, cleared April 28, 2010) and PIEZOTOME 2 (K091331, cleared December 11, 2009).
The Technical Characteristics for Dental Application of PIEZOTOME M+ (Piezoelectric Performances and Irrigation Performances) are similar as the Predicate Device PIEZOTOME 2 (K091331, cleared December 11, 2009). The Bone Surgery Tips for PIEZOTOME M+ are similar as the Bone Surgery Tips of the Predicate Device Piezoelectric System (K100410, cleared April 28, 2010).

Sterilization Validation: The Sterilizability Tests have been performed according to applicable Standards for Re-Usable accessories and Single Use Accessories provided under Sterile State.

Biocompatibility Validation: The Biocompatibility Tests have been performed according to applicable Standards for Accessories in contact to the Patient. Tests were conducted according to the ISO 10993-1 Standard and 510(k) Memorandum - #G95-1 Table 1 "Initial Evaluation Tests for Consideration requirements (Body Contact: External communicating Device – Type of Tissues: Tissue / Bone Dentin Communicating – Contact Duration: A limited less than 24 hours).

VIII – CONCLUSION

Following all information contained in this Pre-Market Notification Submission File, we can declare that the SATELEC PIEZOTOME M+ is Substantially Equivalent (SE) to the SATELEC Predicate Devices Piezoelectric System (K100410, cleared April 28, 2010) and PIEZOTOME 2 (K091331, cleared December 11, 2009).

End of Section

(No other information after this line expect Appendix if applicable)