Satelec - Acteon Group
Argie Zoubroulis
Quality Manager
124 Gaither Drive Suite # 140
Mt. Laurel, New Jersey 08054

April 3, 2018

Re: K172137
Trade/Device Name: PIEZOTOME CUBE
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZI
Dated: March 23, 2018
Received: April 3, 2018

Dear Argie 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.

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,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172137

Device Name
PIEZOTOME CUBE

Indications for Use *(Describe)*
The PIEZOTOME CUBE is an ultrasonic surgical system that supply utilities to and serve as a base for dental tips. The PIEZOTOME CUBE consist of a control unit and handpiece intended for use in intraoral surgery procedures, including osteotomy, osteoplasty, periodontics and implantology.

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
[As Required by 21 CFR 807.92.c]
K172137

I – SUBMITTER

01.a. 510(k) Submitter:

SATELEC
17, Avenue Gustave Eiffel
BP 30216
33708 Merignac Cedex
France
Telephone: 011-33-556-340-607
Fax: 011-33-556-349-292
email: philippe.girard@acteongroup.com

01.b. Contact Person:

Argie ZOUBROULIS
SATELEC
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Telephone: 800-289-6367 Ext. 390
Fax: 856-222-4726
Email: argie.zoubroulis@acteongroup.com

1.c. Establishment Registration Number: 8044015

1.d. Date Prepared: May 2, 2018

1.e. Type of 510(k) submission: Traditional 510(k) Submission.

II – DEVICE

02.a. Trade Name of Device: PIEZOTOME CUBE

02.b. Common Name of Device: Piezoelectric Handpiece and Console

02.c. Classification Regulation: Classification Name : Bone Cutting Instrument and Accessories (21 CFR 872.4120)

02.d. Regulation Identification: 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.

02.e. Medical Device Class: II

02.f. Panel: Dental

02.g. Product Code: DZI

02-h. Subsequent Product Codes: Not Applicable

III – PREDICATE DEVICES

The Substantial Equivalence (SE) of PIEZOTOME CUBE is based on the Predicate Device identified in the Table 01.

Table 01 – Identification of Legally Marketed Predicate Devices

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
PIEZOTOME SOLO PIEZOTOME SOLO LED	SATELEC	DZI	K112188	Feb 03, 2012

IV –DEVICE DESCRIPTION

SATELEC CUBE is an piezoelectric device that uses micro-vibrations of associated Tips, to perform the dental procedures defined in Indication for Use.

PIEZOTOME CUBE consists of a Console, a Multifunction footswitch and a reusable Handpiece.

The Console is the heart of the SATELEC PIEZOTOME CUBE. The Console contains the display board and the motherboard. Ultrasonic Handpiece and Footswitch are connected to the Console. The Touch screen present on the front panel is used to define the settings of the SATELEC PIEZOTOME CUBE (Ultrasonic modes, irrigation flow values).

The Ultrasonic Handpiece is held in the Practitioner's hand. The Ultrasonic Handpiece is connected to the Console via a Handpiece Cord. The Handpiece is dedicated to Dental Bone Surgery procedures. The Ultrasonic Handpiece is equipped with a Piezoelectric Transducer. The Piezoelectric transducer converts the Electrical Signal delivered by the Console into mechanical micro-vibrations. The Ultrasonic Handpiece is reusable and Sterilizable by autoclaving.

Tips are fixed by means of a Wrench at the extremity of the Ultrasonic Handpiece. Tip are in direct contact to the patient. The ultrasonic mechanical vibrations are transmitted to the Tip.

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

V – INDICATION FOR USE

The PIEZOTOME CUBE is an ultrasonic surgical system that supply utilities to and serve as a base for dental tips. The PIEZOTOME CUBE consist of a control unit and handpiece intended for use in intraoral surgery procedures, including osteotomy, osteoplasty, periodontics and implantology.

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

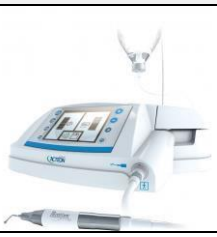
A comparison Between SATELEC PIEZOTOME CUBE and the Predicate Device is present in Table 02.

Table 02 – Comparison Between SATELEC PIEZOTOME CUBE and the Predicate Device

	New Device	Predicate Device #1 (PD#1)	Impact of the differences on Safety / Effectiveness
Trade / Device Name	PIEZOTOME CUBE	PIEZOTOME SOLO	
Knumber	K172137	K112188	
Indication for Use	The PIEZOTOME CUBE is an ultrasonic surgical system that supply utilities to and serve as a base for dental tips. The PIEZOTOME CUBE consist of a control unit and handpiece intended for use in intraoral surgery procedures, including osteotomy, osteoplasty, periodontics and implantology.	The intended use of the SATELEC PIEZOTOME SOLO (or PIEZOTOME SOLO LED available in option) is to supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners.	Similar to PD#1 - No Impact
Intended Use	The intended use of the SATELEC PIEZOTOME CUBE is to supply utilities and to serve as a base for dental tools and accessories for use by qualified dental practitioners.	The intended use of the PIEZOTOME SOLO is to supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners. The PIEZOTOME SOLO is a device designed to perform dental surgery including osteotomies, osteoplasties, periodontal and implant surgery.	Similar to PD#1 - No Impact
Code Product	DZI	DZI	Identical to PD#1 - No Impact
Subsequent product Codes	/	/	Identical to PD#1 - No Impact
Part	872 - Dental devices	872 - Dental devices	Identical to PD#1 - No Impact
Regulation Number	21 CFR 872.4120	21 CFR 872.4120	Identical to PD#1 - No Impact

006 – 510(k) Summary (SMDA Requirements)
S001_Additional Information

Regulation Identification	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	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	Identical to PD#1 - No Impact

	New Device	Predicate Device #1 (PD#1)	Impact of the differences on Safety / Effectiveness
Trade / Device Name	PIEZOTOME CUBE	PIEZOTOME SOLO	
Knumber	K172137	K112188	
	device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw	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	
Regulation Name	Bone Cutting Instrument and Accessories	Bone Cutting Instrument and Accessories	Identical to PD#1 - No Impact
Regulatory Class	II	II	Identical to PD#1 - No Impact
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 - No Impact
Dimensions of the Console			
Height (mm)	160	136	No Impact
Depth (mm)	271	306	No Impact
Width (mm)	251	378	No Impact
Weight (kg)	3.5	3.7	No Impact
Mounting Unit	Table Top	Table Top	Identical to PD#1 - No Impact
Power Supply			
Supply Voltage (VAC)	100 VAC to 230 VAC	100 VAC to 230 VAC	Identical to PD#1 - No Impact
Frequency (Hz)	50 Hz / 60 Hz	50 Hz / 60 Hz	Identical to PD#1 - No Impact
Power Consumption (VA)	150	150	Identical to PD#1 - No Impact
Electrical Safety Classification			
Equipment Classification	Class 1	Class 1	Identical to PD#1 - No Impact
Electrical Type	BF Type	BF Type	Identical to PD#1 - No Impact
Applied Parts on the Console			
Quantity of connectors for Applied Parts	1	1	Identical to PD#1 - No Impact
Localization	Front Panel of the Device	Front Panel of the Device	Identical to PD#1 - No Impact
Internal constitution of the Console			
Power supply	Switch Power Supply	Switch Power Supply	Identical to PD#1 - No Impact
Mother Board Fire aspects	UL94-V0 (self-extinguishing material)	UL94-V0 (self-extinguishing material)	Identical to PD#1 - No Impact
Display Board Fire aspects	UL94-V0 (self-extinguishing material)	UL94-V0 (self-extinguishing material)	Identical to PD#1 - No Impact
External constitution of the Console			
Fire aspects (for Casing)	UL94-V0 (self-extinguishing material)	UL94-V0 (self-extinguishing material)	Identical to PD#1 - No Impact
Pictures			
Picture of the Console			No impact

	New Device	Predicate Device #1 (PD#1)	Impact of the differences on Safety / Effectiveness
Trade / Device Name	PIEZOTOME CUBE	PIEZOTOME SOLO	
Knumber	K172137	K112188	
Picture of the Footswitch			Identical to PD#1 - No Impact
Piezoelectric Performances for Dental Bone Surgery			
Technology	SATELEC PIEZOTOME topology	SATELEC PIEZOTOME topology	Identical to PD#1 - No Impact
Output Ultrasonic frequency (kHz)	28 to 36	28 to 36	Identical to PD#1 - No Impact
Available modes	D1/ D2 / D3 / D4	D1/ D2 / D3 / D4	Identical to PD#1 - No Impact
Nominal specification for Output Current Value in D1 mode (mA)	215.3	215.3	Identical to PD#1 - No Impact
Nominal specification for Output Current Value in D2 mode (mA)	171.2	171.2	Identical to PD#1 - No Impact
Nominal specification for Output Current Value in D3 mode (mA)	123.9	123.9	Identical to PD#1 - No Impact
Nominal specification for Output Current Value in D4 mode (mA)	120.8	120.8	Identical to PD#1 - No Impact
Frequency Modulation for D1 mode (Hz)	60	60	Identical to PD#1 - No Impact
Frequency Modulation for D2 mode (Hz)	60	60	Identical to PD#1 - No Impact
Frequency Modulation for D3 mode (Hz)	60	60	Identical to PD#1 - No Impact
Frequency Modulation for D4 mode (Hz)	30	30	Identical to PD#1 - No Impact
Irrigation Performances			
Irrigation Pump(s)	1	1	Identical to PD#1 - No Impact
Off Irrigation (ml/min)	0	0	Identical to PD#1 - No Impact
Minimum Irrigation Flow Rate (nominal) (ml/min)	10	10	Identical to PD#1 - No Impact
Maximum Irrigation Flow Rate (nominal) (ml/min)	120	120	Identical to PD#1 - No Impact
Localization of the Mains Power Switch			
Power-On / Power-Off	Mains switch localized at the rear of the Device	Mains switch localized at the rear of the Device	Identical to PD#1 - No Impact
User Interface for setting			
User interface for information on settings	LED (Light Emitted Diode)	Monochrome LCD	No Impact
Ultrasonic Power Setting keys	Sensitive areas on front panel	Keys on front panel	No Impact
Irrigation Flow Setting keys	Sensitive areas on front panel	Keys on front panel	No Impact
Footswitch			
Type of Footswitch	Multifunction	Multifunction	Identical to PD#1 - No Impact
Number of actuators on Footswitch	2 Functions	2 Functions	Identical to PD#1 - No Impact
Environmental			

	New Device	Predicate Device #1 (PD#1)	Impact of the differences on Safety / Effectiveness
Trade / Device Name	PIEZOTOME CUBE	PIEZOTOME SOLO	
Knumber	K172137	K112188	
Where used	Usable in all medical premises Except Operating theater / outdoor	Usable in all medical premises Except Operating theater / outdoor	Identical to PD#1 - No Impact
Operating Temperature (°C)	+10 to +30	+10 to +30	Identical to PD#1 - No Impact
Storage Temperature (°C)	0 to +50	-20 to +70	No Impact
Maximum Operating Altitude (m)	2000	2000	Identical to PD#1 - No Impact
Anatomical site	Bones in the oral sphere	Bones in the oral sphere	Identical to PD#1 - No Impact
Handpieces			
Dental Bone Surgery Handpiece	CUBE LED Handpiece	PIEZOTOME SOLO Handpiece	No Impact
Type of Applied Part	Ultrasonic Handpiece	Ultrasonic Handpiece	Identical to PD#1 - No Impact
Technology used for Handpieces	Piezoelectric technology	Piezoelectric technology	Identical to PD#1 - No Impact
Dimensions of the Dental Bone Surgery Handpieces			
Length (mm)	130	130	Identical to PD#1 - No Impact
Maximum Diameter (mm)	23	23	Identical to PD#1 - No Impact
Irrigation Tubing			
Length (mm)	2550	2550	Identical to PD#1 - No Impact
Principle of irrigation	Peristaltic tape	Peristaltic tape	Identical to PD#1 - No Impact
Dimensions of the Footswitch			
Width (mm)	173	173	Identical to PD#1 - No Impact
Height (mm)	140	140	Identical to PD#1 - No Impact
Depth (mm)	176	176	Identical to PD#1 - No Impact
Ingress Protection Rating (IPxx)	IPX1	IPX1	Identical to PD#1 - No Impact
Cleaning			
Dental Bone Ultrasonic Handpiece	Re-usable, Cleanable	Re-usable, Cleanable	Identical to PD#1 - No Impact
Unit Casing	Re-usable, Cleanable	Re-usable, Cleanable	Identical to PD#1 - No Impact
Sterilization / Sterile State			
Dental Bone Ultrasonic Handpiece	Sterilizable 132°C / 4 min	Sterilizable 132°C / 4 min	Identical to PD#1 - No Impact
Irrigation Tubing	Provided under Sterile State - Single Use	Provided under Sterile State - Single Use	Identical to PD#1 - No Impact
Biocompatibility			
Ultrasonic Handpiece material in contact to Patient	Polyphenylsulfone (PPSU) used in Medical Application	Polyphenylsulfone (PPSU) used in Medical Application	Identical to PD#1 - No Impact
Standards			
Safety Standard	IEC 60601-1	IEC 60601-1	Identical to PD#1 - No Impact
EMC Standard	IEC 60601-1-2	IEC 60601-1-2	Identical to PD#1 - No Impact
Summary of Major Changes			
Major Changes - User Interface for setting			
User interface for Setting	Sensitive areas with Light Emitted Diode (LED)	Monochrome LCD	No Impact
Ultrasonic Power Setting	Accessible on Sensitive area on front panel	Accessible on Keyboard on front panel	No Impact

	New Device	Predicate Device #1 (PD#1)	Impact of the differences on Safety / Effectiveness
Trade / Device Name	PIEZOTOME CUBE	PIEZOTOME SOLO	
Knumber	K172137	K112188	
Irrigation Flow Setting	Accessible on Sensitive area on front panel	Accessible on Keyboard on front panel	No Impact
Handpieces			
Dental Bone Surgery Handpiece	CUBE LED Handpiece	PIEZOTOME SOLO Handpiece	No Impact
Pictures of Dental Bone Surgery Handpieces			

A lot of features and characteristics of PIEZOTOME CUBE are identical to the Predicate Device #1. The Identified differences have no impact on the Substantial Equivalence. Moreover, the identified Major Changes have no impact on the Substantial Equivalence.

VII – PERFORMANCE DATA

Electromagnetic Compatibility Test: The Electromagnetic Compatibility Tests have been performed according to IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances -- requirements and tests (Recognition Number 19-12).

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.

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.

Performance Testing bench: The comparison of performances between PIEZOTOME CUBE and Predicate Device has been performed. The Technical Characteristics for PIEZOTOME CUBE (Piezoelectric Performances, Frequency Modulations and Irrigation Performances) are similar as the Predicate Device PIEZOTOME SOLO (K112188, cleared February 03, 2012).

Sterilization Validation: The Sterilizability Tests of SATELEC CUBE LED Handpiece have been performed according to applicable Standards for Re-Usable accessories (i.e., ISO 17665-1, ISO 17665-2, AAMI ST55, and AAMI TIR 30).

Cleaning Validation: Cleaning validation of the PIEZOTOME CUBE was conducted per the FDA Guidance Document entitled, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" dated March 17, 2015.

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). SATELEC CUBE LED Handpiece is the same as SATELEC PIEZOTOME SOLO Handpiece used with the Predicate Device PIEZOTOME SOLO (K112188, cleared February 03, 2012).

VIII –CONCLUSION

Following all information contained in this Pre-Market Notification Submission File, we can declare that the SATELEC PIEZOTOME CUBE is Substantially Equivalent (SE) to the SATELEC Predicate Device PIEZOTOME SOLO (K112188, cleared February 03, 2012).

End of Section

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