August 19, 2024

Mectron S.p.A.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K242432
Trade/Device Name: MT-Bone
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: Class II
Product Code: DZI, ELC
Dated: August 15, 2024
Received: August 16, 2024

Dear Prithul Bom:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242432

Device Name

MT-Bone

Indications for Use *(Describe)*

MT-Bone is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for:
- Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic and surgical endodontic procedures;
- Scaling applications, including:
  Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  ° Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  ° Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
  ° Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

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.

mectron
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K242432

Section: 510(k) Summary in accordance with 21 CRF 872.4120

Data: August 08, 2024

1. Administrative Information

Type of 510(k) submission: .....Traditional 3P 510(k)

Device Common Name:.....Drill, Bone, Powered Scaler, Ultrasonic

Regulation description:.....Bone cutting instrument and accessories

Proprietary names of the device: .....MT-Bone

Manufacturer: .....Mectron S.p.A.
Via Loreto, 15/a
Carasco - GE 16042, Italy

FDA Registration Number:.....3003933619

510(k) Owner: .....Mectron S.p.A.
Via Loreto, 15/a
Carasco - GE 16042, Italy

510(k) Preparer and Contact:.....Ms. Chiara Acunzo
Regulatory Affairs Senior Specialist
Mectron S.p.A.

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2. Device identification:

Regulatory Class: .....Class II

Classification Regulation:....21 CFR 872.4120: Bone cutting instrument and accessories

Product Codes: .....Primary [DZI]
.....Secondary [ELC]

Review Panel:.....Dental

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3. Identification of the Predicate / Reference Devices

Predicate device:

The Substantial Equivalence of the subject device is based on the predicate device.

Trade Name	Manufacturer	Product Code	510(k) Number
PIEZOSURGERY TOUCH	Mectron S.p.A.	DZI, ELC	K122322

4. Device description

MT-Bone is a piezoelectric ultrasonic device designed for oral bone surgery.
MT-Bone uses piezoelectric ultrasound technology to generate mechanical micro vibrations that can cut, drill or abrade through mineralized structures using appropriate inserts.
This allows an efficient and safe action which preserves the integrity of the osteotomized surfaces.
The micrometric, ultrasonic vibrations of the inserts provide greater precision and a selective action compared to traditional methods such as drills or oscillating saws (which act with macro vibrations), therefore minimizing traumatic effect on soft tissues. Depending by the Indication for use a lot of different type of inserts are available in Mectron portfolio.

5. Indications for Use

MT-Bone is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for:

- Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic and surgical endodontic procedures;
- Scaling applications, including:
  - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  - Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
  - Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

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6. Comparison of the proposed device and the predicate device

A comparison of the subject device with the predicate device is shown in the following Table 1.1.

	Table 1.1. Comparison Table for determination of Substantial Equivalence between MT-Bone device and Predicate Device			
	Item for comparison	**MT-Bone** **Subject Device**	**PIEZOSURGERY TOUCH** **Predicate Device - K122322**	**Identical / Different**
1	Manufacturer	MECTRON SPA Via Loreto 15/a 16042 Carasco - Italy	MECTRON SPA Via Loreto 15/a 16042 Carasco - Italy	Identical to Predicate Device
2	510(k) Number	Subject of this submission	K122322	N/A
3	Regulation panel	Dental	Dental	Identical to Predicate Device
4	Regulation Number	21 CFR 872.4120	21 CFR 872.4120	Identical to Predicate Device
5	Product Code	Primary Product code: DZI (Bone Cutting Instrument And Accessories Subsequent Product Code: ELC Scaler, Ultrasonic	Primary Product code: DZI (Bone Cutting Instrument And Accessories Subsequent Product Code: ELC Scaler, Ultrasonic	Identical to Predicate Device
6	Classification	Class II	Class II	Identical to Predicate Device
7	Device type	Tabletop device	Tabletop device	Identical to Predicate Device
8	Function	MT-Bone 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.	PIEZOSURGERY TOUCH 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.	Similar to Predicate Device. Optimized device setting for PIEZOSURGERY channel. Dedicated channel for bone hole preparation addressed to Implantology indication for use (PIEZODRILL channel). These differences do not impact safety or clinical performance.
9	Indications for use	MT-Bone is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for: • Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including	PIEZOSURGERY TOUCH is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for: • Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal	Identical to Predicate Device

	Table 1.1. Comparison Table for determination of Substantial Equivalence between MT-Bone device and Predicate Device			
	Item for comparison	**MT-Bone** **Subject Device**	**PIEZOSURGERY TOUCH** **Predicate Device - K122322**	**Identical / Different**
		implantology, periodontal surgery, surgical orthodontic and surgical endodontic procedures; • Scaling applications, including: - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits; - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning; - Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation; - Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.	surgery, surgical orthodontic and surgical endodontic procedures; • Scaling applications, including: - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits; - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning; - Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation; - Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.	
10	Intended patient population	Infant, children, adolescent, and adult population	Infant, children, adolescent, and adult population	Identical to Predicate Device
11	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Identical to Predicate Device
12	Biocompatibility	Biocompatible	Biocompatible	Identical to Predicate Device
13	Parts need to be sterilized prior use?	YES	YES	Identical to Predicate Device
14	Technological Characteristics (Mechanism of action)	Piezoelectric ultrasonic technology which generates mechanical micro-vibrations of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Piezoelectric ultrasonic technology which generates mechanical micro-vibrations of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Identical to Predicate Device
15	Main Components of the device	• Control unit with integrated irrigation peristaltic pump, electric power supply and ultrasonic generator. • PIEZOSURGERY MT and PIEZODRILL MT ultrasonic handpieces and cord. • Torque wrenches to tighten the inserts on the handpiece. • Footswitch with cord. • Bracket for irrigation solution bag. • Power supply cord. • Range of insert tips to be used according to the dental applications defined by intented use. • Other accessories (make reference to the "List of Accessories" of the eSTAR submission)	• Control unit with integrated irrigation peristaltic pump, electric power supply and ultrasonic generator. • Piezosurgery ultrasonic handpiece and cord. • Torque wrench to tighten the inserts on the handpiece. • Footswitch with cord. • Bracket for irrigation solution bag. • Power supply cord. • Range of insert tips to be used according to the dental applications defined by intented use. • Other accessories (make reference to the "List of Accessories" of the eSTAR submission)	Similar to Predicate Device This difference does not impact safety or clinical performance

	Table 1.1. Comparison Table for determination of Substantial Equivalence between MT-Bone device and Predicate Device			
	Item for comparison	**MT-Bone** **Subject Device**	**PIEZOSURGERY TOUCH** **Predicate Device - K122322**	**Identical / Different**
16	Interfaces Handpieces	Two different piezoelectric handpieces can be connected to the device control unit. Dedicated connectors and input ports ensure correct connections. Both handpieces encase piezoelectric transducers responsible for generation and transmission of micrometric vibrations to the insert tips connected at ultrasonic frequencies. - PIEZOSURGERY MT handpiece is intended for all the claimed indications for use of the device; PIEZODRILL MT handpiece is dedicated to implant site preparation. Its usage in conjunction with dedicated insert tips allows the precise, efficient and safe drilling of holes of different diameters and depths within hard mineralized tissue	One piezoelectric handpiece can be connected to the device control unit. PIEZOSURGERY TOUCH handpiece, and all claimed indications for use of the device can be performed using it."	Similar to Predicate Device. PIEZOSURGERY MT handpiece comprises exactly the same piezozelectric transducer of the PIEZOSURGERY TOUCH handpiece and can perform all the indications for use claimed by the PIEZOSURGERY TOUCH device. The PIEZODRILL MT handpiece comprises a piezoelectric transducer specifically designed to allow more efficient bone drilling when used in conjunction with dedicated insert tips. Optimized with l higher efficiency of the former, as a consequence of improved drilling efficiency and intraoperative usability. These differences do not impact safety or clinical performance.
17	Interfaces Footswitch	Footswitch connected to the control console by means of a cord	Footswitch connected to the control console by means of a cord	Identical to Predicate Device
18	Irrigation System	Irrigation bag connected to a peristaltic pump. Adjustable irrigation flow rate.	Irrigation bag connected to a peristaltic pump. Adjustable irrigation flow rate.	Identical to Predicate Device
19	Ultrasound Frequency	24 kHz to~36 kHz	24 kHz to~36 kHz	Identical to Predicate Device
20	Vibration amplitude	10 µm ÷ 250 µm	10 µm ÷ 250 µm	Identical to Predicate Device
21	Electrical power input	100-240 V ~ 50/60 Hz	100 - 240 V - 50/60 Hz.	Identical to Predicate Device
22	Electrical safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Identical to Predicate Device
23	Electromagnetic Compatibility	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Identical to Predicate Device
24	Device contains software?	YES	YES	Similar to Predicate Device This difference does not impact safety or clinical performance
25	User interface	Touch screen (monitor)	Touch screen (keypad)	Similar to Predicate Device Optimized user interface. This difference does not impact safety or clinical performance
26	Connectivity	Wireless	No connection	Optimization of the device with the introduction of IoT board (ESP32) for wireless connection. The FW/SW that the IoT board manages is a non-medical SW.

	Table 1.1. Comparison Table for determination of Substantial Equivalence between MT-Bone device and Predicate Device			
	Item for comparison	**MT-Bone** **Subject Device**	**PIEZOSURGERY TOUCH** **Predicate Device - K122322**	**Identical / Different**
				The connection does not impact safety, clinical performance, basic performance, or the intended purpose of the medical device.
27	FW/SW - Device management	C	Assembler	Similar to Predicate: A porting from Assembler to C was performed maintaining the same management and the same work mode. This difference does not impact safety or clinical performance
28	FW/SW - UI management	Qt e C++	C	Similar to Predicate: This difference does not impact safety or clinical performance. They are consequences of the User interface optimization.
29	FW/SW – Internal communications management communication protocol.	SSTP-EVO Protocol	SPI Communication	Optimization of the device. Communication between microprocessors is enhanced with the new proprietary This difference does not impact safety or clinical performance.
30	Dimensions: (HxWxD) Weight (approx)	330 x 260 x 162 mm (L x l x H) 4,7kg	300 x 250 x 95 mm (L x l x H) 3,2 Kg	Similar to Predicate Device since all the devices have dimensions and weights consistent with the tabletop use.

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Substantial Equivalence Discussion

The proposed device and the predicate device PIEZOSURGERY TOUCH (K122322 cleared on 12/06/2012) have the intended use substantially identical.

The proposed device and the predicate device share also many identical features, including identical/equivalent principle of operation and technological characteristics.

The differences identified in the above table 1.1 clearly have no impact on safety or effectiveness of the device. Any differences identified in above table does not introduce any new questions regarding safety and effectiveness.
These considerations are also confirmed by the performance test carried out in comparison with the predicate device PD1.

The data presented in this submission demonstrates the identities existing between the MT-Bone device and the predicate device, and thus support a finding of substantial equivalence between the subject device and the referenced predicated device, already in commercial distribution in the United States.

7. Summary of Non-Clinical Testing

The following table summarizes the relevant bench performance testing concluded on the MT-Bone system.

Bench performance testing category	Test description
Electrical safety	The device was positively tested according to IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 80601-2-60:2019 for electrical safety. According to the results and evidence reported within test report the device MT-Bone is considered electrically safe.
EMC	The device was positively tested according to IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 for electromagnetic compatibility. According to the results and evidence reported within test report the device MT-Bone has demonstrated electromagnetic compatibility.
Biocompatibility	The device was positively tested according to ISO 10993-1 and FDA guidance Use of International Standard ISO 10993-1. Biological evaluation was done on the device system with identification of the critical devices and components. The Biological Evaluation Plan and Report summarizes the endpoints identified for the device according to its intended use (time and type of contact). All tests passed successfully. The testing showed that the relevant parts of the subject devices are biocompatible.
Reprocessing	The reusable device and components (handpiece, torque wrench and insert) were validated in terms of cleaning (both manual and automated) and for sterilization processes. All tests passed successfully. The testing showed the efficacy of the reprocessing procedures applied to the relevant parts of the subject devices.
Software and Firmware	The software used in the various modules embedded within the devices was developed and positively validated according to: • IEC 62304+A1. • The FDA guidance " Content of Premarket Submissions for Device Software Functions" • The requirements of clause 14 of IEC/EN 60601-1 third edition.

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Bench performance testing category	Test description
	• The requirements of CEI EN 60601-1-4+A1 (identical to the International Standard IEC 60601- 1- 4+A1), for the countries in which the standard is still valid.
Performance Testing – Bench	A series of tests evaluated the efficacy and safety of reusable inserts, providing valuable insights into their performance and ensuring the highest standards of quality and patient well-being. For boosted PIEZOSURGERY inserts the pre-clinical tests confirmed: • The improvement of performance with respect to PIEZOSURGERY touch; • The requirements on amplitude and frequency; • The reduced time to complete the procedures with respect to PIEZOSURGERY touch. For PIEZODRILL inserts: • The requirements on intra osseous temperature; • The requirements on soft tissue safety; • The requirements on amplitude and frequency; • The reduced time to complete the procedure with respect to PIEZOSURGERY touch.
Usability Testing	The usability tests included: - simulation of the installation, configuration and assembly of the device in accordance with the user manual. - Understanding of the graphical interface relating to functional screens and support screens. - clinical procedures evaluation on implant site preparation, osteotomy and osteoplasty. The usability tests passed successfully. Analyzing all the KOLs feedback and evaluations, the usability of the device, considering in particular all the new aspects (GUI, PIEZOSURGERY MT and PIEZODRILL MT handpieces, K11 torque wrench, PD inserts) results validated according to the test objectives. Furthermore, the validation in terms of clinical procedures highlights a well perceived increase of the performance of the most representative inserts used for osteotomy, osteoplasty and pilot hole preparation.
Cadaver Lab	The cadaver lab confirmed the requirements on performance, safety, benefits and usability. The evaluation process conducted by clinicians in the cadaver lab has been comparative between the new device MT-Bone and its predicate PIEZOSURGERY touch. By comparing the MT-Bone system with the predicate device, clinicians have assessed its improvements, advantages, or potential limitations in clinical applications for which it is intended. This comparative analysis has also collected data to demonstrate the equivalence of the MT-Bone device to its predicate legacy PIEZOSURGERY touch device and the compliance to the relevant general safety and performance requirements.
Distribution testing	Transport simulation (according to ASTM D4169), verification of the sterile barrier maintenance of the single use components and electrical safety verification on the device after transport simulation were done on the device system configuration. The verification of the sterile barrier maintenance of the single use components passed all the performed tests. All the controls on the components after the tests performed in external laboratories were conducted and all the items worked properly. Electrical safety tests, done internally by V&V department, resulted in measurements within the acceptable ranges.

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Bench performance testing category	Test description
	To conclude, all tests in this report are considered successfully passed, so the packaging of the device is compliant with all relative standards that specify the transportation rules.

8. Summary of Clinical Testing

Animal or clinical testing were not required to prove MT-Bone substantial equivalence when compared to the predicate device.

9. CONCLUSION

Based on the comparative analysis and testing contained within this submission, it is concluded that the MT-Bone device has intended use, safety and effectiveness profile, and technological characteristics, substantially equivalent to the identified predicate device which are already in commercial distribution in the United States.