June 19, 2025

Leone S.p.A.
℅ Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K242944
Trade/Device Name: Leone Orthodontic Implant TAD (Temporary Anchorage Device)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: OAT
Dated: May 21, 2025
Received: May 21, 2025

Dear Paul Dryden:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Andrew I. Steen -S

Andrew I. Steen
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)*

K242944

Device Name

Leone Orthodontic Implant TAD (Temporary Anchorage Device)

Indications for Use *(Describe)*

The Leone Orthodontic Implant TADs (Temporary Anchorage Devices) are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.

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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16-Jun-25

Leone Orthodontic Implant TAD

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SUBMISSION CORRESPONDENT

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Person: Paul Dryden

DEVICE

Trade or Proprietary Name: Leone Orthodontic Implant TAD (Temporary Anchorage Device)
Regulation Description: Endosseous dental implant
Regulation number: 872.3640
Classification Name: Implant, Endosseous, Orthodontic
Product Code : OAT

PREDICATE DEVICE

Trade or Proprietary Name: K110392, PSM LOMAS/BENEFIT Screws
Regulation Description: Endosseous dental implant
Regulation number: 872.3640
Classification Name: Implant, Endosseous, Orthodontic
Product Code : OAT

INDICATION FOR USE

The Leone Orthodontic Implant TADs (Temporary Anchorage Devices) are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.

DEVICE DESCRIPTION

Leone TADs are miniscrews made of titanium for surgical use (ISO 5832-3/ASTM F136). These orthodontic miniscrews are self-drilling with right-hand thread and they are available in an 8mm length. These devices are supplied sterile and sterilized by gamma irradiation.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	SUBJECT Device (K242944)	**PREDICATE Device (K110392)**	**Significant Difference**
Manufacturer	Leone S.p.A.	Psm Medical Solutions	-
Trade Name	Leone Orthodontic Implant TADs	PSM LOMAS/BENEFIT Screws	-
Regulation Description	Endosseous dental implant	Endosseous dental implant	Same
Regulation Number	872.3640	872.3640	Same
Product Code	OAT	OAT	Same
Indications for Use	The Leone Orthodontic Implant TADs (Temporary Anchorage Devices) are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.	The PSM LOMAS / BENEFIT Screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.	Same
Material	Titanium Alloy ISO 5832-3/ASTM F136	Titanium Alloy ISO 5832-3/ASTM F136	Same
Anatomical site	Maxillary and mandibular bone.	Maxillary and mandibular bone.	Same
Design	Leone TADs are self-drilling with right-hand thread.	The PSM LOMAS/BENEFIT Screws are self-drilling with right-hand thread.	Same
Length (mm)	TADs VL 8 mm	Lengths 7, 9, 11, 13, 15 mm	Similar The length of 8mm is within the range (7mm to 15mm) of the predicate device

	SUBJECT Device (K242944)	PREDICATE Device (K110392)	Significant Difference
Body Diameter	TADs VL Ø2.0mm	LOMAS screws (Ø1.5mm and Ø2.0mm), BENEFIT screws (Ø2.0mm and Ø2.3mm)	Same
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Same
Packaging	Packaged in an inner sterile plastic vial (primary sterile package) inside a sealed plastic blister and protected by an external cartoon box.	Packaged in a sealed sterile plastic blister (primary sterile package) and protected by an external cartoon box.	Same
Single Use/Reuse	Single use only	Single use only	Same
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Material is identical to reference K070483

The information provided demonstrates that the Leone TADs are substantially equivalent to the predicate device with respect to indications for use, device design, function, and performance with respect to technological characteristics. The predicate devices are made of the same material as the subject device, titanium alloy (ASTM F136), the same material as our device.

The minor differences in overall length between the subject and predicate devices do not affect the overall performance of the device. The Leone TADs 8mm length is within the range of the predicate's length offerings (7mm to 15mm).

The technological differences between the subject device and the predicate devices do not impact substantial equivalence, and substantial equivalence is demonstrated by testing in accordance with ASTM F543.

Thus, according to the similarities specified in the above comparison table between the proposed device and the predicate device in terms of indications for use, materials, geometry, technology and performance, as supported by the results of the nonclinical testing here below specified, the Leone Orthodontic Implant TAD results are substantially equivalent to the Predicate PSM LOMAS/BENEFIT Screws device.

NONCLINICAL TEST

The following performance data were provided to support the determination of substantial equivalence.

Performance Testing

-INSERTION TEST according to the standards ASTM F543 "Standard Specification and Test Methods for Metallic Medical Bone Screws" and ISO 19023 "Dentistry - Orthodontic anchor screws" to evaluate the penetration capacity.

- FAILURE TORQUE TEST according to the standards ASTM F543 "Standard Specification and Test Methods for Metallic Medical Bone Screws", ISO 19023 "Dentistry - Orthodontic anchor screws" and

ISO 5832-3 “Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy” to determine the torsion characterization.
- PULL-OUT TEST according to the standards ASTM F543 “Standard Specification and Test Methods for Metallic Medical Bone Screws” to compare the retention capacity of the miniscrews.
-BENDING TEST for a comparative flexural strength test.
-SEM SURFACE ANALYSIS to assess the residual contamination of the device
-FUNCTIONAL TEST OF THE SCREW as torsion resistance tests for the accessories of the devices.
The results of the analysis demonstrate that the subject device and the legally marketed predicate device performances are substantially equivalent for the assessed endpoints, because the outcomes of the test are comparable between the proposed and the predicate device.

Biocompatibility
Leone Orthodontic Implant TAD is manufactured using the same manufacturing process and proven materials as the previously cleared FDA Leone dental implants (K070483); which support the biological safety of subject devices.

Additional biocompatibility testing is not necessary to support the biological safety of Leone Orthodontic Implant TADs. Nevertheless, the biocompatibility evaluation and testing were conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA’s Biocompatibility Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

Sterilization Testing
Sterilization validation testing has been performed on the Leone Orthodontic Implant TADs in accordance with ISO11137-1, ISO 11137-2 and ISO 11137-3. The sterilization procedure is validated to a Sterility Assurance Level (SAL) of 10^{-6}.

CLINICAL TESTS
No clinical performance data were provided to demonstrate substantial equivalence.

CONCLUSIONS
The Leone Orthodontic Implant TAD and the predicate device have substantially equivalent indications for use, same raw material, same range of physical dimensions, and same characteristics in labelling and packaging. In addition, the substantial equivalence to the predicate device has been confirmed through non-clinical testing. Therefore, the subject device, Leone Orthodontic Implant TAD, is determined to be substantially equivalent (SE) to the predicate device, PSM LOMAS/BENEFIT Screws (K110392).