September 04, 2024

Proimtech Saglik Urunleri Anonim Sirketi
Hakan Cevik
General Manager
Imes Sitesi, No:3 Dudullu Osb Mahallesi Imes 305.Sokak
Istanbul, Istanbul 34773
TURKEY

Re: K231502
Trade/Device Name: Proimtech Mini Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: May 12, 2024
Received: August 8, 2024

Dear Hakan Cevik:

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,

Sherrill Lathrop Blitzer

for Andrew 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231502

Device Name
Mini Screws

Indications for Use *(Describe)*
The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. The orthodontic screw is intended in patients aged 12 years and older.

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
510k number: K231502
Mini Screws
Proimtech Saglik Urunleri Anonim Sirketi

Company Name	:	Proimtech Saglik Urunleri A.S.
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Official Contact : Hakan Cevik, General Manager of Proimtech Saglik Urunleri Anonim Sirketi
Phone Number : +90 535 355 51 00
E-Mail : hakancevik@bilimplant.com

DEVICE INFORMATION

Preparation Date : September 04, 2024

Device Trade Name : Mini Screws

Common Name : Mini Screw

Classification Name : screw, fixation, bone (21 CFR 872.3640)

Device Class : II

Product Code : OAT

Regulation Number : 872.3640

Review Panel : Dental

INDICATION FOR USE

The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. The orthodontic screw is intended in patients aged 12 years and older.

DEVICE DESCRIPTION

The Mini Screws system has been designed to provide a firm anchorage point in the oral cavity for orthodontic treatment. Mini screws are manufactured with CP Ti Gr 4 and are SLA treated. The Mini Screw system is designed to be applied with different orthodontic solutions and is versatile enough to satisfy different clinical cases. Titanium orthodontic mini screws are intended to provide fixed anchorage for orthodontic treatment used by implanting in the maxillary and mandibular bone.

These mini screws used for anchoring purposes can be divided into 3 parts as head, neck and body.

➢ Head Part:

Head part, it is the part where both the rotational force necessary for the screw to move in the bone is applied and where it is used as a fulcrum for the force to occur. The heads of the mini screws are designed in the shape of a hexagon in which the screwdriver bit is fully inserted. The hole in the head is designed for the attachment of chains, elastic wires or springs to initiate the necessary tooth movements.

➢ Neck Part:

Neck part It is the part between the gingiva and the cortical bone, has no grooves and a shiny surface. The maximum compression of the screw occurs in this area and during insertion into the cortical bone.

➢ Body Part:

Body part is the threaded part of the screw that remains in the bone. The thickness of the inner part of the body (core) provides the resistance of the screw against fracture and the groove depth provides the resistance of the screw against pulling.

The head part of the screws is cross-shaped or button-shaped and this part is the part where the necessary rotational force is applied to ensure that the screw advances in the bone. It is also the part where mechanics such as wire, spring or rubber are connected to the teeth to be moved. The neck part is designed to be smooth to make the use more comfortable, especially in patients with thin gingival biotype. The body part is designed as cylindrical and grooved in order to keep the screw fixed in the bone. The tip is angled conical for ease of application.

➢ Length of Screws:

Screw lengths vary between 5 mm and 16 mm. The length of the screw is determined by some factors such as the angle of application, thickness of the mucosa, bone quality and proximity of neighboring structures.

➢ Screw Diameters:

Screw diameters vary between 1.4 and 2 mm. The stability of the screws is affected by the screw surface area in contact with the cortical bone. As the diameter increases, the contact surface area will increase and the stability will also increase.

➢ Surface Characteristics of Screws:

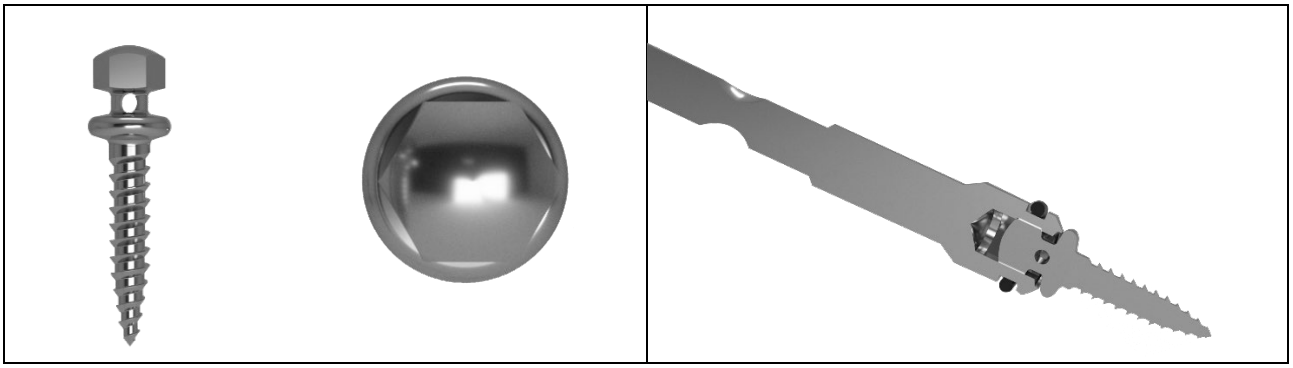
The tips of the mini screws with Ø 1.4 mm, Ø 1.65 mm and Ø 2 mm diameters used for orthodontic anchorage have a sandblasted and acid etched (SLA) surface structure and have a surface roughness of 1.5-2 Ra. Since similar screws on the market are not expected to be osseointegrated, the surfaces of most of them are not treated. However, in order to apply high anchorage force and increase screw stability, the ends of these products are treated with "Sandblasted, large-grid, acid etched" (SLA) process, which is sandblasting followed etching.

➢ Groove Structure of Screws:

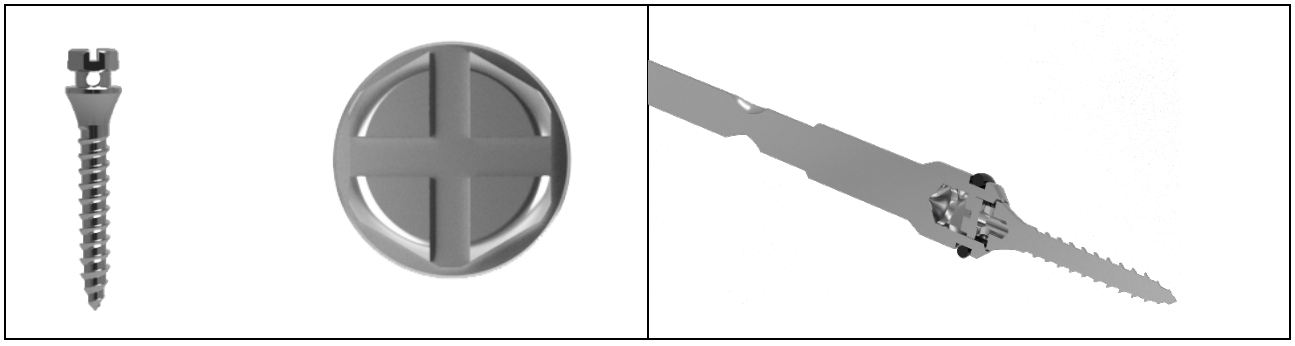
Screws can be classified as self-tapping (ST) and self-drilling (SD) according to their thread design. Our mini screws, which are used for tooth mobilization are placed directly as SD without predrilling. However, in areas with dense cortical bone, the need for pilot slot preparation with drills may rarely be encountered. Our mini screws are placed with a hand tool or a low-torque rotary instrument (contra-angle handpiece) at the recipient site.

➢ Connection Type of Products:

The connection of the mini screws features a hexagon socket.



Hexagon Connection Structure



Length of SLA Surface Treatment Area:

All our mini screws have 1/2 apical part with SLA surface.

MATERIALS:

Only materials approved for medical purposes are used in the manufacture of products: **Pure Titanium Grade 4** according to standard ISO 5832-2 and ASTM F67-13.

PERFORMANCE AND SAFETY SPECIFICATION

Surface Characterization:

SLA is used to roughen the surface by applying a strong acid to the surface sandblasted with coarse grainy particles. The SLA technique has been used as an alternative to TPS coatings to achieve better surface chemistry and topography. This process is applied in combination after osseointegration to achieve macroroughness and micropits, as well as grit-sandblasting and acid etching to increase surface roughness.

MRI Compatibility:

The Mini Screw has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Mini Screws in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction**.**

The product design has been made to include all kinds of safety and performance requirements considering the intended use and location of the product. In this direction, especially;

- ✓ The product is manufactured from pure titanium (Grade 4) raw material in accordance with EN 1642, TS EN ISO 19023, ISO 5832-2 and ASTM F67-13 Standard.
- ✓ Our products are packaged in a Class 100,000 Clean Room according to ISO 11607 standard to ensure microbiological safety. They are then sterilized with Gamma radiation in accordance with the parameters specified in our user manual.
- ✓ The gamma sterilization method declared by us has been validated in accordance with EN 11137-1/2 Standard.
- ✓ The biocompatibility of our finished products has been carried out in accordance with EN 10993-1 Standard.
- ✓ Tests for the mechanical strength of our products have been carried out in accordance with TS EN ISO 19023 and ASTM F543 Standard.

Primary Predicate Device and Reference Device

For primary device Mini Screws: K161197; Orthodontic screw, OSSTEM Implant Co., Ltd.

For reference device Mini Screws: K152297; OBS Anchorage Screw, BOMEI

For reference device Mini Screws: K191041; Orthodontic Fixation Screw (Smart Anchor Miniscrew), GNI Co., LTD

For reference device Mini Screw: K122069; Storm Mini Screw, Lancer Orthodontics

SUMMARIES OF TECHNOLOGICAL CHARACTERISTICS & SUBSTANTIAL EQUIVALENCE DISCUSSION

Technological Characteristics	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Mini Screws	**Orthodontic screw**	**OBS Anchorage Screw**	**Orthodontic Fixation Screw (Smart Anchor Miniscrew)**	**Storm Mini Screw**	**Dual Top Screw System**
510(k) Number	K231502	K161197	K152297	K191041	K122069	K161335
Manufacturer	Proimtech Saglik Urunleri A.S	OSSTEM Implant Co., Ltd.	BOMEI	GNI Co., LTD	Lancer Orthodontics	Jeil Medical Corporation
Product Code	OAT	OAT	OAT	OAT	OAT	OAT
Indications for Use	The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only. The orthodontic screw is intended in patients aged 12 years and older.	The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only	Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been complete.	The Orthodontic Fixation Screw[Smart Anchor Miniscrew] is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	The Storm Mini Screw is a threaded titanium dental implant screw intended to provide a fixed anchorage point for !he attachment .of orthodontic appliances and facilltate the orthodontic movement of, teeth. it is used temporarily and must be	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.

					removed after orthodontic treatment has been completed. The Storm Mini Screw is provided sterile and is intended for single use only.	
Design						
Material	Titanium (Ti Grade 4, ASTM F67)	Ti-6Al-4V ELI, ASTM F 136	Stainless Steel (ISO 5832-1:2007/ ASTM F138-13) Titanium Alloy (ISO 5832-3:1996/ ASTM F136-13)	Ti-6Al-4V ELI, ASTM F 136	Ti-6Al-4V ELI, ASTM F 136	Titanium Alloy (ASTM F136)
Body Diameter	Ø1.4 mm Ø1.65 mm Ø2 mm	Ø1.2 mm Ø1.4 mm Ø1.6 mm Ø1.8 mm	Ø1.5 Ø2	Ø1.2 mm Ø1.4 mm Ø1.6 mm Ø1.8 mm Ø2 mm	Ø1.5 mm Ø2 mm	Ø1.3 – Ø2.5

Length	Ø1.4 x 6 mm Ø1.4 x 7 mm Ø1.4 x 8 mm Ø1.4 x 9 mm Ø1.4 x 10 mm Ø1.65 x 6 mm Ø1.65 x 7 mm Ø1.65 x 8 mm Ø1.65 x 9 mm Ø1.65 x 10 mm Ø1.65 x 11 mm Ø1.65 x 12 mm Ø2 x 6 mm Ø2 x 7 mm Ø2 x 8 mm Ø2 x 9 mm Ø2 x 10 mm Ø2 x 11 mm Ø2 x 12 mm Ø2 x 14 mm	6 mm 8 mm 10 mm	Ø1.5 x 8 mm Ø1.5 x 10 mm Ø1.5 x 12 mm Ø2 x 8 mm Ø2 x 10 mm Ø2 x 12 mm Ø2 x 14 mm	6 mm 8 mm 10 mm	8 mm 10 mm	5 mm – 16 mm
Single Use	Yes	Yes	Yes	Yes	Yes	Yes
Surface	Sandblasted Large grit Acid etched (SLA)	Acid etching	---	Machined (not acid etched)	---	No surface treatment
Sterilization	Radiation Sterile	Radiation Sterile	Non-Sterile (Steam sterilized by user)	Non-Sterile (Steam sterilized by user)	Sterile via beta irradiation	Non-Sterile (Steam sterilized by user) or Gamma-Sterilized

Shelf life	5 years	8 years	5 years	5 years	5 years	-
Target population	Professional use only – qualified dentists, orthodontist or oral surgeon. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only - qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	People having orthodontia work	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.
Principle of Operation	Anchorage mini screws are used to move the teeth.	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Anchorage mini screws are used to move the teeth.	Anchorage mini screws are used to move the teeth.	Dental and orthodontic soecialists offices	Anchorage mini screws are used to move the teeth.
Substantial Equivalence Discussion						

Similarities

The device has similar characteristics compared to the primary predecessor device in the following respects. Indication for use, product code, design, diameter, disposable, intended population and operating principle.

Difference

The differences between the subject device and the predicate device is the surface treatment. However, testing data such as mechanical testing provided in the submission show that these differences do not raise issues in performance. Additionally, the subject device are available in slightly different length compared to the predicates, however the such dimensional changes do not raise any performance concerns.

Conclusion

On the basis of the above discussion, it is concluded that the device in question is substantially equivalent to the primary predicate device.