January 03, 2025

Proimtech Saglik Urunleri Anonim Sirketi
Hakan Cevik
Official Correspondent
Dudullu OSB Mahallesi Imes Sanayi Sitesi E Blok 501. Sokak N
o:25 Dudullu OSB Mahallesi Imes Sanayi Sitesi C Blok 305.
Istanbul, UMRANIYE 34775
TURKEY

Re: K233419
Trade/Device Name: GBR System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: December 9, 2024
Received: December 9, 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)*
K233419

Device Name
GBR System

Indications for Use *(Describe)*
The Guided Bone Regeneration (GBR) System is used to stabilize and fix bone grafts, bone filling materials and/or barrier membranes used for bone regeneration in the oral cavity.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510k number: K233419

GBR System

Proimtech Saglik Urunleri Anonim Sirketi

Company Name	:	Proimtech Saglik Urunleri A.S.
Authorised Person / Title	:	Hakan Çevik / General Manager
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E-Mail : hakancevik@bilimplant.com

DEVICE INFORMATION

Preparation Date: December 31, 2024

Device Trade Name: GBR System

Common Name: GBR Kit

Classification Name: Intraosseous fixation screw or wire (21 CFR 872.4880)

Device Class: II

Product Code: DZL

Regulation Number: 872.4880

Review Panel: Dental

INDICATION FOR USE

The Guided Bone Regeneration (GBR) System is used to stabilize and fix bone grafts, bone filling materials and/or barrier membranes used for bone regeneration in the oral cavity.

DEVICE DESCRIPTION

		
It provides block bone graft fixation.	It stabilizes the graft particles by creating a tent effect under the membrane.	It fixes the membrane.

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.

Non-Clinical Tests Conducted

Substantial equivalence to the predicate devices was determined by the following tests:

- ✓ The product is manufactured from pure titanium (Grade 1641) raw material in accordance with EN 1642, TS EN ISO 19023, ISO 5832-2 and ASTM F67-13 Standard.
- ✓ Our biocompatibility assessment is leveraged from our FDA approved application K231100. The devices in K231100 are made of the same materials and underwent the same manufacturing processes compared to the subject device.
- ✓ Our Insertion Torque, Fracture Torque, Pull-out tests, which we had performed in neutral laboratories for the mechanical strength of our products, were carried out in accordance with TS EN ISO 19023 and ASTM F543-23 Standards.
- ✓ Our non-sterile products should be sterilized with Autoclave before use by the users in accordance with the parameters specified in our user manuals.
- ✓ The autoclave sterilization method declared by us has been validated in accordance with EN 17665-1 Standard. Our device has been verified by sterility tests.

MRI Compatibility:

Rationale for relying on the Woods et al. Article

Non-clinical worst-case MRI review was performed to evaluate the Proimtech devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. The rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque. The GBR System is labeled as MR conditional.

Legally Marketed Device to Which

Claim Substantial Equivalence:

For primary device GBR System: K011698; Straumann GBR System Straumann USA

For reference device GBR System: K182881; Bone Tack, OSSTEM Implant Co., Ltd.

For reference device GBR System: K182881; Bone Screw, OSSTEM Implant Co., Ltd

For reference device GBR System: K161857; Tenting Screw, Salvin Dental

SUMMARIES OF TECHNOLOGICAL CHARACTERISTICS & SUBSTANTIAL EQUIVALENCE DISCUSSION

Technological Characteristics	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	GBR System	Straumann GBR System	Bone Tack	Tenting Screw	Bone Screw
510(k) Number	K233419	K011698	K182881	K161857	K182881
Manufacturer	Proimtech Saglik Urunleri A.S	Straumann USA	Osstem Implant Co., Ltd.	Salvin Dental	Osstem Implant Co., Ltd.
Product Code	DZL	JEY and DZL	DZL	DZL	DZL
Indications for Use	The Guided Bone Regeneration (GBR) System is used to stabilize and fix bone grafts, bone filling materials and/or barrier membranes used for bone regeneration in the oral cavity.	The Straumann Guided Bone Regeneration (GBR) System is used to stabilize and fixate bone grafts, bone filling materials, and/or barrier membranes used for regeneration of bone in the oral cavity. The GBR technique can make it possible for the placement of dental implants in previously unsuitable sites.	It is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.	The Salvin Tenting Screw is used to stabilize, fixate, and/or support bone grafts, bone filling materials and /or barrier membranes used for regeneration of bone in the oral cavity.	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity
Design					
Material	Titanium (Ti Grade 4, ASTM F67)	Titanium (Ti Grade 4, ASTM F67)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)
Diameter	1 1.2 1.5 2	1.2 mm 1.5 mm	2.5 mm	1.5	1.4 mm 1.95 mm

Length	Ø1*3.7 mm Ø1.2*6 mm Ø1.2*8 mm Ø1.2*10 mm Ø1.2*12 mm Ø1.2*14 mm Ø1.5*6 mm Ø1.5*7 mm Ø1.5*8 mm Ø1.5*9 mm Ø1.5*10 mm Ø1.5*11 mm Ø1.5*12 mm Ø2*5 mm Ø2*6 mm Ø2*7 mm	3.0 mm 4.0 mm 5.0 mm 7.0 mm 8.0 mm 9.0 mm 10.0 mm 12.0 mm 14.0 mm	3.0 mm	7 mm 8 mm 9 mm	Ø1.4: 4.0 mm 6.0 mm 8.0 mm Ø1.95: 8.0 mm 10.0 mm 12.0 mm 14.0 mm 16.0 mm
Single Use	Yes	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Sterile	Non-sterile	Sterile
Principle of Operation	The function of proposed device is used in application for fixating or stabilizing barrier membranes in GBR	The function of predicate devices is used in application for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas	The function of proposed device is used in application for fixating or stabilizing barrier membranes in GBR	The Salvin Tenting Screw System is a set of bone screws and instrumentation. The system consists of a set of screws (one diameter and three lengths) and the driver used to implant these screws. The devices are delivered non-sterile. The screws are made from titanium alloy (Ti-6Al4V ELI), as described by ASTM F136.	The function of proposed devices is used in application for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas
Substantial Equivalence Discussion					

Similarities

The device has similar characteristics compared to the predicate and reference devices in the following respects. Indication for use, design, sterilization, disposable and operating principle.

Difference

The material, diameter and length dimensions of the device in question are slightly different from the the predicate and reference devices. However, as a result of the insertion torque, fracture torque and pull-out tests, it was determined that there was no significant difference in product performance and that this difference did not affect the substantial equivalence.

Discussion

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