May 19, 2026

Bernhard Förster GmbH (Bernhard Foerster Ltd.)
% Juan Tezak
Consultant
Compliance 4 Devices, Ltd.
118 Prive Cir
Delray Beach, Florida 33445

Re: K260268
Trade/Device Name: OrthoEasy Pal; OrthoEasy Pal Long Neck
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: April 17, 2026
Received: April 17, 2026

Dear Juan Tezak:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260268

Device Name
OrthoEasy Pal;
OrthoEasy Pal Long Neck

Indications for Use *(Describe)*
FORESTADENT OrthoEasy® anchorage screws are intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth **in adolescents greater than 12 years of age and adults.** It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.

The device is not intended for palatal expansion or for use as a prosthodontic or dental implant component.

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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Bernhard Förster GmbH (Bernhard Foerster Ltd.)

510(K) Summary
K260268

I)	Preparation Date	May 19th 2026
II)	Applicant	
	Submitter	Bernhard Förster GmbH (Bernhard Foerster Ltd.)
	Address	Westliche Karl-Friederich-Strass 151 75172 Pforzheim, Germany
	Telephone	+49 7231 459-16
	Contact	Mr Stefan Förster
	E-Mail	regulatory@forestadent.com
III)	Device	
	Trade Name	OrthoEasy Pal; Ortho easy Pal Long Neck
	Common Name	Endosseous dental implant
	Classification Name	Implant, Endosseous, Orthodontic
	Regulation Number	872.3640
	Product Code	OAT
IV)	Predicate Device	
	510(k)	K110275
	Applicant	Bernhard Förster GmbH (Bernhard Foerster Ltd.)
	Trade Name	Ortho Easy Pin
	Classification Name	Implant, Endosseous, Orthodontic
	Regulation Number	872.3640
	Product Code	OAT
	Reference Devices	
	510(k)	K110392
	Applicant	PSM Lomas
	Trade Name	BENEFIT Screw
	Classification Name	Implant, Endosseous, Orthodontic
	Regulation Number	872.3640
	Product Code	OAT
	510(k)	K202691
	Applicant	Craniofacial Technologies
	Trade Name	Ortholock Anchorage Devices
	Classification Name	Implant, Endosseous, Orthodontic
	Regulation Number	872.3640
	Product Code	OAT

V) Device Description

OrthoEasy® Pal and OrthoEasy® Pal Long Neck orthodontic implants are screws made of the high-quality metal alloy titanium 6-aluminium 4-vanadium (Ti6Al4V (Titanium Grade 5, ASTM F136, EN ISO 5832-3)). The implant body is cylindrical and has a sharp apex in conical shape. The thread of the implant is self-tapping and self-drilling which makes it a non- surgical orthodontic implant. The implant head is octagonal that ensures precise torque transfer during insertion. All products include a sleeve between the thread and the functional head to protect soft tissue.

VI) Intended Use/Indication for Use

VII) FORESTADENT OrthoEasy® anchorage screw is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.

The device is not intended for palatal expansion or for use as a prosthodontic or dental implant component.

VIII) Comparison of Technological Characteristics

	Bernhard Foerster GmbHOrtho Easy Pin	Bernhard Foerster GmbH Ortho Easy Pal	Comparison Result
FDA Product Code	OAT	OAT	Same
K Number	K110275	K260268	N/A
FDA Device Classification Name	Implant, Endosseous	Implant Endosseous	Same
Intended use	This devise is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.	FORESTADENT OrthoEasy® anchorage screw is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only. The device is not intended for palatal expansion or for use as a prosthodontic or dental implant component.	Similar The age range for which it can be used is specified, and it is clarified that the term "Pal" in the name does not refer to use in the palatal region. None of this affects the substantial equivalence of the use of both devices.
Target Population	Adolescents greater than 12 years of age and adults that need of teeth alignment correction.	Adolescents greater than 12 years of age and adults that need of teeth alignment correction.	Same
Location of use (hospital, home, ambulance, etc.)	Use only for professional dentists or orthodontics.	Use only for professional dentists or orthodontics.	Same
Design	Diameter 1.7mm length ranges from 6 – 12 mm	Diameter 1.7mm, 2.3 mm length ranges from 8 - 14 mm	Different
Head Design	Cross-shaped slot	Internal Thread	Different
Performance	Self-trapping/self-drilling screws	Self-trapping/self-drilling screws	Same
Standard met	ISO 7405	ISO 7405	Same
Materials	Titanium alloy ASTM F136	Titanium alloy ASTM F136	Same
Biocompatibility	Titanium alloy in medical grade according ASTM F 136 is acceptedfor endosseous implants.	Cytotoxicity test as per ISO 10993-5 was perform showing non cytotoxic effect	Same
Sterility	Non-sterile	Non-sterile	Same
Mechanical safety	Tensile strength of material according to ASTM F 136 diameter 1,7mm, fracture-proof during implantation. See also material test reports comparing torque in different materials.	• Mechanical testing was performed to determine the pull-out, torsion, and torque of the screw in accordance with ISO 19023:2018, Dentistry – Orthodontic anchor screws; and ASTM F543-17, Standard Specification and Test	Same

		Methods for Metallic Medical Anchor screw. • Bending test for a comparative flexural strength test.	

Head equivalence

	PSM Lomas – BENEFIT Screw	Bernhard Foerster GmbH Ortho Easy Pal and Ortho Easy Pal Long Neck	Comparison Result
FDA Product Code	OAT	OAT	Same
K Number	K110392	K260268	N/A
FDA Device Classification Name	Implant, Endosseous	Implant Endosseous	Same
Intended use	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. Screws are intended for single use only.	FORESTADENT OrthoEasy® anchorage screw is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only. The device is not intended for palatal expansion or for use as a prosthodontic or dental implant component.	Similar The clarification of the term Pal in the name does not affect the substantial equivalence in the use of both devices.
Indication for use	See intended use.	See intended use.	Same
Target Population	Patients in need of teeth alignment correction.	Patients in need of teeth alignment correction.	Same
Location of use (hospital, home, ambulance, etc.)	Use only for professional dentists or orthodontics.	Use only for professional dentists or orthodontics.	Same
Design			Similar Both designs are similar, differing only in how they attach to the insertion tool. The subject device features a hexagon design, while the predicate features a quadrant. Mechanical testing conducted on the subject device confirmed that its design functions exactly as intended.

Measures	Diameter 2.0mm, 2.3mm lengthranges from 6 – 12 mm	Diameter 1.7mm, 2.3 mm length ranges from 8 - 14 mm	Similar The dimensions are similar. The subject device has a smaller diameter (1.7 mm vs. 2.0 mm) but a greater initial length (8 mm vs. 6 mm). Mechanical testing conducted on the subject device confirmed that its design functions exactly as intended, despite these dimensional differences.
Head Design	Square with Internal Thread	Octagon with Internal Thread	Different (See the design section in this table)
Performance	Self-trapping/self-drilling screws	Self-trapping/self-drilling screws	Same
Standard met	ISO 7405	ISO 7405	Same
Materials	Titanium alloy ASTM F136	Titanium alloy ASTM F136	Same
Biocompatibility	Titanium alloy in medical grade according ASTM F 136 is accepted for endosseous implants.	Cytotoxicity test as per ISO 10993-5 was perform showing non cytotoxic effect	Same
Sterility	Non-sterile	Non-sterile	Same

Placement location

	Orthолock Anchorage Devices Craniofacial Technologies	Bernhard Foerster GmbH Ortho Easy Pal and Ortho Easy Pal Long Neck	Comparison Result
FDA Product Code	OAT	OAT	Same
K Number	K202691	K260268	N/A
FDA Device Classification Name	Implant, Endosseous	Implant Endosseous	Same
Intended use	The Ortholock 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.	FORESTADENT OrthoEasy® anchorage screw is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only. The device is not intended for palatal expansion or for use as a prosthodontic or dental implant component.	Similar The clarification of the term Pal in the name does not affect the substantial equivalence in the use of both devices.

Target Population	Patients in need of teeth alignment correction.	Patients in need of teeth alignment correction.	Same
Design			Different Both designs are similar, differing in how the prosthetic abutments are attached. The subject device features a titanium screw, whereas the abutments on the predicate device thread into its head. Mechanical testing conducted on the subject device confirmed that its design functions exactly as intended.
Measures	Diameter 1.8mm Threaded Body: 7.4mm Smooth Neck: 2.2mm and 4.2mm Head: 1.9mm Overall Length: 11.5mm and 13.5mm	Diameter 1.7mm, 2.3 mm Length ranges from 8 - 14 mm	Similar The dimensions are similar. Mechanical testing conducted on the subject device confirmed that its design functions exactly as intended, despite these dimensional differences.
Head Design	Externally Threaded, Head for the attachment of orthodontic appliances	Octagon with Internal Thread	Different (See the design section in this table)
Performance	Self-trapping/self-drilling screws	Self-trapping/self-drilling screws	Same
Standard met	ISO 7405	ISO 7405	Same
Materials	Titanium alloy ASTM F136	Titanium alloy ASTM F136	Same
Surface Treatment	Anodized	Anodized	Same
Biocompatibility	Titanium alloy in medical grade according ASTM F 136 is accepted for endosseous implants.	Cytotoxicity test as per ISO 10993-5 was perform showing non cytotoxic effect	Same
Sterility	Non-sterile	Non-sterile	Same
Placement locations	Suitable locations for Ortholock placement include the paramedian or midsagittal region of the hard palate and the anterior palate. Do not place the Ortholock Anchorage Device screws in the sutures of people with developing bone or sutures that are not completely fused.	Multiple locations in the oral cavity included palatal region. Do not place the Ortholock Anchorage Device screws in the sutures of people with developing bone or sutures that are not completely fused.	Same

IX) Summary of Non-Clinical Testing

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

- Mechanical testing was performed to determine the pull-out, torsion, and torque of the screw in

accordance with ISO 19023:2018, Dentistry – Orthodontic anchor screws; and ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Anchor screw.

- Bending test for a comparative flexural strength test.
- Biological assessment has been performed according to ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and to the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff", for the subject devices. Cytotoxicity testing according to ISO 10993-5 Biological Evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity and no cytotoxicity was observed.
- Sterilization validation testing has been performed 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. No microbial growth was observed.

X) Summary of Clinical Testing

No clinical testing was performed, the determination of substantial equivalence is supported by nonclinical testing.

XI) Conclusion

The results obtained demonstrate that the system's performance and stability are substantially equivalent to the predicate devices.