February 23, 2022

Dentium Co., Ltd.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K213599
Trade/Device Name: SuperLine
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 21, 2022
Received: January 24, 2022

Dear Kevin Thomas:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213599

Device Name

SuperLine

Indications for Use *(Describe)*

SuperLine® implants are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine® implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length implants are indicated for delayed loading.

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
K213599
SuperLine
Dentium Co., Ltd.

February 23, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Dentium Co., Ltd. 76, Changnyong-daero 256beon-gil Suwon-si, Gyeonggi-do, 16229, Korea Telephone +82-070-7098-7568 Fax +82-31-888-5595
Official Contact	Eunsang Lee, Team Manager of Regulatory Affairs
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	SuperLine
Common Names	Endosseous dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K160965, SuperLine, Dentium Co., Ltd.

Additional Predicate Devices
K123988, AnyOne™ Internal Implant System, MegaGen Implant Co., Ltd
K120414, OsseoSpeed™ Plus, Astra Tech AB
K023113, Replace TiUnite Endosseous Implant, Nobel Biocare USA, Inc.
K092035, Bicon Implants with a 2.5mm Internal Connection, Bicon, LLC

INDICATIONS FOR USE STATEMENT

SuperLine® implants are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine® implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length implants are indicated for delayed loading.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add dental implants to the SuperLine components cleared in K160965. This submission includes two series of implants: SuperLine FXSxxxxB Series and SuperLine FXSxxxx Series.

The FXSxxxxB Series has a machined collar height that ranges from 0.03 mm (on the 3.6 mm body diameter implant) to 0.6 mm (on the 5.0 mm body diameter implant). All FXSxxxxB Series implants have an endosseous length of 7 mm, and threaded lengths ranging from of 6.98 mm to 6.4 mm. Other than the endosseous length of 7 mm, the subject device FXSxxxxB implants are identical in design and sizes to SuperLine implants cleared in K160965.

The FXSxxxx Series has machined collar 1.5 mm in height for all implant body diameter sizes. For body diameters 4.0 mm to 5.8 mm, the collar has a reverse taper. All FXSxxxx Series implants have an endosseous length of 7 mm, and a threaded length of 5.5 mm. The FXSxxxx series implant design has not been cleared previously by FDA for any body diameter or length.

The subject device SuperLine dental implants are summarized in the following table.

Implant Series	Body Ø, mm	Platform Ø, mm	Collar Height, mm	Total Length, mm
FXSxxxxB Series	3.6	3.6	0.03	7
	4.0	4.0	0.2	7
	4.5	4.5	0.35	7
	5.0	5.0	0.6	7
FXSxxxx Series	3.6	3.6	1.5	7
	4.0	4.0	1.5	7
	4.5	4.5	1.5	7
	5.0	5.0	1.5	7
	5.0	6.0	1.5	7
	5.8	7.0	1.5	7

All subject device implants are manufactured from the same unalloyed titanium conforming to ASTM F67 and have the same surface treatment (S.L.A., Al_2O_3 blasted and acid etched) as the dental implants cleared in K160965.

All subject device implants are compatible with previously-cleared abutments and prosthetic components from Dentium Co., Ltd., including those cleared in K192436, K141457, and K041368.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

gamma irradiation sterilization for all subject devices (to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2, referenced from K160965);

bacterial endotoxin testing (referenced from K160965) including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 on samples of water used in manufacturing on a bimonthly basis and on samples from sterilized product on a quarterly basis to demonstrate all sterile product meets a limit of $\leq$ 20 EU/device;

shelf life testing (referenced from K160965) including testing of samples according to ASTM F1929 and F88/F88M (packaging sterile barrier) and sterility testing of product;

and surface area analysis showing substantial equivalence to K092035.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the additional predicate devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate device K160965, except for the addition of the language regarding delayed loading for single tooth cases on 7 mm length implants.

All IFUS include language regarding placement in the mandible or maxilla for support of prosthetic devices; differences in the specific wording do not change the intended use (functional and esthetic rehabilitation of the edentulous mandible or maxilla) of these devices. The IFUS for K123988, K120414, K023113, and K092035 include language regarding surgical protocols, immediate and delayed loading, and limitations for specific device sizes. These differences in the specific wording of the IFUS also do not change the intended use of these devices.

The subject device FXSxxxxB Series implants are identical in design and sizes (implant body diameter, platform diameter) to SuperLine implants cleared in K160965 except for the length of 7 mm. The FXSxxxxB Series implants have a machined collar height that ranges from 0.03 mm (on the 3.6 mm body diameter implant) to 0.6 mm (on the 5.0 mm body diameter implant); this feature is the same as the implants cleared in K160965. All FXSxxxxB Series implants have a total (overall) length of 7 mm, and endosseous threaded and surface treated lengths ranging from of 6.98 mm to 6.4 mm.

The subject device FXSxxxx Series implants are provided in the same body diameters and platform diameters as implants cleared in K160965, but have a total (overall) length of 7 mm, and have a machined collar height of 1.5 mm (for all implant sizes). This machined collar height is substantially equivalent to that of implants cleared in K023113 (Replace TiUnite Endosseous Implant, Nobel Biocare USA, Inc.).

The subject device implants are provided in body diameters of 3.6 mm to 5.8 mm, each with an overall length of 7 mm. This range of subject device implant diameters, with 7 mm length, is substantially

equivalent to that of implants cleared in K120414 (diameters 3-5.4 mm in lengths 6-17mm, OsseoSpeed™ Plus, Astra Tech AB), and to that of implants cleared in K123988 (diameters 4.8-7.3 mm with a length of 7 mm, AnyOne™ Internal Implant System, MegaGen Implant Co., Ltd).

The subject device implants with the overall length of 7 mm are substantially equivalent in surface area to Bicon implants cleared in K092035. An analysis was performed comparing the surface area of the subject device implant with smallest implantable surface area to the surface area of the Bicon implant with a diameter of 4 mm and length of 5 mm.

All subject device implants are manufactured from the same unalloyed titanium and have the same grit-blasted and acid-etched surface treatment as the dental implants cleared in K160965. The subject device implants are compatible with previously-cleared abutments and prosthetic components from Dentium Co., Ltd., including those cleared in K192436, K141457, and K041368.

All subject device implants components are provided sterile by gamma irradiation, the same sterilization method used in K160965.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical materials. The subject device, the primary predicate device, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

Features	Subject Device	Primary Predicate Device	Additional Predicate Device	Additional Predicate Device	Additional Predicate Device	Additional Predicate Device
	K213599	**K160965**	**K123988**	**K120414**	**K023113**	**K092035**
	SuperLine	**SuperLine**	**AnyOne™ Internal Implant System**	**OsseoSpeed™ Plus**	**Replace TiUnite Endosseous Implant**	**Bicon Implants with a 2.5mm Internal Connection**
	Dentium Co., Ltd.	**Dentium Co., Ltd.**	**MegaGen Implant Co., Ltd**	**Astra Tech AB**	**Nobel Biocare USA, Inc.**	**Bicon, LLC**
Indications for Use Statement	SuperLine® implants are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine® implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length implants are indicated for delayed loading.	SuperLine is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient''s chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. *Complete Indications for Use statement is provided in this section.*	The Nobel Biocare Replace TiUnite Endosseous Implant is intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore patient's chewing function. This may be accomplished using a two stage surgical procedure or a single stage surgical procedure. If the single stage surgical procedure is used, these implants may be loaded immediately following insertion - provided - at least four implants are placed and splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foraminae) where good initial stability of the implants with or without bi-cortical anchorage, can most often be obtained.	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
Reason for Predicate Device	**Not applicable**	**Implant designs, materials, manufacturing, sterilization**	**Implant design, diameters and shorter length**	**Implant design, diameters and shorter length**	**Implant body with machined collar**	**Performance testing data (surface area analysis)**
Product Codes	DZE	DZE	DZE, NHA	DZE	DZE	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Implant Designs						
Prosthetic Interface Connection	Tapered conical hex	Tapered conical hex	Internal hex	Internal taper	Internal Tri-Channel	Internal
Implant Sizes Body/Platform Diameter and Length	**SuperLine FXSxxxxB Series** Body/Platform Diameters 3.6/3.6; 4.0/4.0; 4.5/4.5; 5.0/5.0 mm Each in 7 mm length only	**SuperLine II (US Marketing Name)** Body/Platform Diameters 3.6/3.6; 4.0/4.0; 4.5/4.5; 5.0/5.0 mm Each in lengths of 8, 10, 12, 14 mm and Body/Platform Diameters 5.0/6.0; 5.8/7.0 mm Each in lengths of 8, 10, 12 mm	Body diameters 3.9 mm – 7.3 mm (‘normal thread’) 4.8 mm – 8.3 mm (‘deep thread’) 4.8, 5.3, 6.3, 7.3 mm (‘special length’) Lengths (‘Height’ in 510(k) Summary) 7.0 – 14.5 mm (normal and deep thread) 7.0 mm (special length)	Body diameters 3.0 mm – 5.4 mm Lengths 6 mm – 17 mm Body diameter 3.0 mm, lengths 8-15 mm Body diameter 3.6 mm, lengths 6-17 mm Body diameter 4.2 mm, lengths 6-17 mm Body diameter 4.8 mm, lengths 6-17 mm Body diameter 5.4 mm, lengths 6-17 mm	Body diameters 3.5, 4.3, 5.0, 6.0 mm Lengths 10, 13, 16 mm	**2.5 mm Well Short Implants** Body diameter 4.0 mm, lengths 5, 8, 11 mm Body diameter 4.5 mm, lengths 8, 11 mm
Body/Platform Diameters Length	**SuperLine FXSxxxx Series** 3.6/3.6; 4.0/4.0; 4.5/4.5; 5.0/5.0; 5.0/6.0; 5.8/7.0 mm Each in 7 mm length only					
Implant Material	All implants: unalloyed titanium, ASTM F67	All implants: unalloyed titanium, ASTM F67	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4	Ti-6Al-4V alloy
Implant Endosseous Surface	All implants: S.L.A., Al_2O_3 blasted and acid etched	All implants: S.L.A., Al_2O_3 blasted and acid etched	S.L.A.	OsseoSpeed (micro-roughened and fluoride-modified surface)	TiUnite (titanium oxide layer)	Integra-CP® (hydroxyapatite coated), Integra-Ti® (grit-blasted and acid etched)
Implant Placement	All implants: bone level	All implants: bone level	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*