January 23, 2020

Dentium Co., Ltd.
Byung-Sun Kim
RA Team Manager
150, Eondong-ro
Giheung-gu
Yongin-si 446-914
REPUBLIC OF KOREA

Re: K192436
Trade/Device Name: Healing Abutments and Cover Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 21, 2020
Received: January 23, 2020

Dear Byung-Sun Kim:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192436

Device Name
Healing Abutments and Cover Screws

Indications for Use *(Describe)*
Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.

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

1. Company

	Submitter
Name	Dentium Co., Ltd.
Address	150, Eondong-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea (16985)
Phone/Fax	Tel. +82-70-7098-8806, Fax. +82-31-8019-9131
Contact person	Byung-sun Kim / RA bskim@dentium.com
Summary Date	01/17/2020

2. Device Name

Proprietary name	:	Healing Abutments and Cover Screws
Regulation number	:	21 CFR 872.3630
Regulation Description	:	Endosseous dental implant abutment
Product code	:	NHA
Device class	:	Class II
Classification Panel	:	Dental Products Panel
Reviewing Branch	:	Dental Devices Branch

3. Predicate Device

Primary Predicate

K052957 Implantium Abutments

Reference Predicate

K041368 Implantium
K112045 SimpleLine II Abutment System
K141457 Dentium Implantium® and SuperLine® Abutments
K153268 NR Line Implant System

K172640 Dentium Implantium & SuperLine Prosthetics

4. Indication for use

Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.

5. Description

The purpose of this submission is to change the sterilization method of Healing Abutments and Cover Screws. These devices which have been provided non-sterile will be sterilized by gamma radiation.

Healing Abutments are used provisionally as an accessory to endosseous dental implant during healing period to prepare gingival tissue for acceptance of a final abutment. Healing Abutments are designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final abutment. Cover Screws are used provisionally as an accessory to protect the inner features of the implant.

The Healing Abutments and Cover Screws are prefabricated and made of Ti-6Al-4V ELI (ASTM F136). These devices are sterilized using gamma radiation method and intended for single use only.

6. Performance Data

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

• Gamma radiation sterilization validation according to ISO 111137-1 and ISO 11137-2, demonstrating a sterility assurance level (SAL) of 10^{-6}.

• Accelerated and real time aging studies according to ASTM F1980 demonstrating a shelf life.

• Biocompatibility of Ti-6Al-4V ELI (ASTM F136) demonstrated by the referenced Dentium submission, K041368, using the identical materials and manufacturing processes including sterilization as the subject device.

7. Technological Characteristics

The following comparison table of the technological characteristics of the subject device and the predicate devices outlines and provides the similarities and the substantial equivalency of the subject device and the predicate.

7.1 Healing Abutment

Comparison of Characteristics

	Subject device	**Primary Predicate**	**Reference predicate**			
Device name	Healing Abutments and Cover Screws	Implantium Abutments (Healing Abutment)	Implantium (Healing Abutment)	SimpleLine II Abutment System (Healing Abutment)	NR Line Implant System (Healing Abutment)	Dentium Implantium & SuperLine Prosthetics (Healing Abutment)
Manufacturer	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.
510(k) Number	K192436	K052957	K041368	K112045	K153268	K172640
Indication for use	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Implantium Prosthetics is intended for use as an aid in prosthetic rehabilitation.	The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	The SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation.	The NR Line Implants System 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. NR Line Implant System is indicated also for immediate loading when	Dentium Implantium® & SuperLine® Prosthetics are intended for use as an aid in prosthetic rehabilitation.

					good primary stability is achieved and with appropriate occlusal loading.	
Materials	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Form	Preformed	Preformed	Preformed	Preformed	Preformed	Preformed
Connection type	Internal	Internal	Internal	Internal	Internal	Internal
Sterilization	Sterile (Gamma Radiation)	Non-sterile	Sterile (Gamma Radiation)	Non-sterile	Non-sterile	Non-sterile
Use	Prescription	Prescription	Prescription	Prescription	Prescription	Prescription
Single Use Only	Yes	Yes	Yes	Yes	Yes	Yes

Dimension comparison

	Image	**Dimension (mm)**	
Subject device (K192436)		Diameter	4.04 / 4.10 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 5.50 / 5.54 / 5.64 / 5.75 / 6.50 / 6.54 / 6.64 / 6.75 / 7.64 / 8.64 / 9.64
		Length	8.70 / 10.91 / 10.93 / 11.04 / 11.15 / 12.41 / 12.44 / 12.55 / 12.65 / 12.66 / 14.42 / 14.44 / 14.55 / 14.66
		Diameter	4.16 / 4.53 / 5.02 / 5.23 / 6.22 / 6.43
		Length	10.52 / 10.55 / 12.26 / 12.28 / 14.25 / 14.27
		Diameter	4.80 / 6.50
		Length	6.15 / 6.30 / 7.15 / 7.30 / 8.15 / 8.30 / 9.15 / 9.30
		Diameter	3.70 / 4.30 / 5.50 / 6.50 / 7.50 / 8.50 / 9.50
		Length	8.10 / 8.60 / 10.10 / 12.10
		Diameter	4.04 / 4.12 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 5.50 / 5.45 / 5.64 / 5.75 / 6.50 / 6.54 / 6.64 / 6.74 / 7.54 / 7.64 / 8.54 / 8.64 / 9.54 / 9.64
		Length	8.88 / 8.89 / 8.90 / 10.81 / 10.83 / 10.96 / 11.05 / 11.06 / 11.09 / 12.31 / 12.34 / 12.45 / 12.55 / 12.56 / 12.57 / 14.32 / 14.34 / 14.51 / 14.56
Predicate device			
K052957		Diameter	4.04 / 4.10 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 5.50 / 5.54 / 5.64 / 5.75 / 6.50 / 6.54 / 6.64 / 6.75 / 7.64 / 8.64 / 9.64
		Length	8.70 / 10.91 / 10.93 / 11.04 / 11.15 / 12.41 / 12.44 / 12.55 / 12.65 / 12.66 / 14.42 / 14.44 / 14.55 / 14.66

K041368		Diameter	4.16 / 4.53 / 5.02 / 5.23 / 6.22 / 6.43
		Length	10.52 / 10.55 / 12.26 / 12.28 / 14.25 / 14.27
K112045		Diameter	4.80 / 6.50
		Length	6.15 / 6.30 / 7.15 / 7.30 / 8.15 / 8.30 / 9.15 / 9.30
K153268		Diameter	3.70 / 4.30 / 5.50 / 6.50 / 7.50 / 8.50 / 9.50
		Length	8.10 / 8.60 / 10.10 / 12.10
K172640		Diameter	4.04 / 4.12 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 5.50 / 5.45 / 5.64 / 5.75 / 6.50 / 6.54 / 6.64 / 6.74 / 7.54 / 7.64 / 8.54 / 8.64 / 9.54 / 9.64
		Length	8.88 / 8.89 / 8.90 / 10.81 / 10.83 / 10.96 / 11.05 / 11.06 / 11.09 / 12.31 / 12.34 / 12.45 / 12.55 / 12.56 / 12.57 / 14.32 / 14.34 / 14.51 / 14.56

1) Similarities

The subject Healing Abutments have the same characteristics for the followings compared to the primary predicate device.

- Indication for use, Material, Connection type, Dimension

The subject Healing Abutments have the same dimensions cleared under K052957, K041368, K112045, K153268 and K172640.

2) Differences

The subject Healing Abutments have the different characteristic for the following compared to the primary predicate device.

- Sterilization Method

3) Discussion

The purpose of this submission is to change the sterilization method of Healing Abutments previously cleared under K052957, K041368, K112045, K153268 and K172640. These Healing Abutments which have been provided non-sterile will be sterilized by gamma radiation. In terms of sterilization method there is difference between the subject device and primary predicate device. However, the reference device K041368 is sterilized via gamma radiation as the subject device. And the sterilization method of subject device was validated according to ISO 111137-1 and ISO 11137-2, demonstrating a sterility assurance level (SAL) of 10^{-6}.

In conclusion, the subject device is substantially equivalent to the predicate device because it is verified that the difference does not affect substantial equivalence.

7.2 Cover Screw

Comparison of Characteristics

	Subject device	Primary Predicate	Reference predicate		
Device name	Cover Screw	Implantium (Cover Screw)	SimpleLine II Abutment System (Cover Screw)	NR Line Implant System (Cover Screw)	Dentium Implantium® and SuperLine® Abutments (Cover Screw)
Manufacturer	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.
510(k) Number	K192436	K052957	K112045	K153268	K141457
Indication for use	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Implantium Prosthetics is intended for use as an aid in prosthetic rehabilitation.	The SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation.	The NR Line Implants System 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. NR Line Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.
Materials	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Form	Preformed	Preformed	Preformed	Preformed	Preformed
Sterilization	Sterile (Gamma Radiation)	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Use	Prescription	Prescription	Prescription	Prescription	Prescription
Single Use Only	Yes	Yes	Yes	Yes	Yes

Dimension comparison

	Image	Dimension (mm)	
Subject device (K192436)		Diameter	3.18 / 3.37 / 4.12
		Length	6.36 / 6.88 / 8.92
		Diameter	3.10 / 3.50
		Length	4.70 / 5.70
		Diameter	3.50 / 4.30
		Length	5.40 / 5.75
		Diameter	3.55
		Length	6.35
Predicate device			
K052957		Diameter	3.18 / 3.37 / 4.12
		Length	6.36 / 6.88 / 8.92
K112045		Diameter	3.10 / 3.50
		Length	4.70 / 5.70
K153268		Diameter	3.50 / 4.30
		Length	5.40 / 5.75
K141457		Diameter	3.55
		Length	6.35

1) Similarities

The subject Cover Screws have the same characteristics for the followings compared to the primary predicate device.

- Indication for use, Material, Dimension

The subject Cover Screws have the same dimensions cleared under K052957, K112045, K153268 and K141457.

2) Differences

The subject Cover Screws have the different characteristic for the following compared to the primary predicate device.

- Sterilization Method

3) Discussion

The purpose of this submission is to change the sterilization method of Cover Screws previously cleared under K052957, K112045, K153268 and K141457. These Cover Screws which have been provided non-sterile will be sterilized by gamma radiation. In terms of sterilization method there is difference between the subject device and primary predicate device. However the sterilization method of subject device was validated according to ISO 111137-1 and ISO 11137-2, demonstrating a sterility assurance level (SAL) of 10^{-6}.

In conclusion, the subject device is substantially equivalent to the predicate device because it is verified that the difference does not affect substantial equivalence.

8. Conclusion

Based on the information provided, the subject device is substantially equivalent to the predicate devices.