November 19, 2019

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

Re: K191634
Trade/Device Name: Scan Abutments and Comfort Caps
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 18, 2019
Received: September 20, 2019

Dear Byung-sun Kim:

This letter corrects our substantially equivalent letter of November 4, 2019.

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 -S

for Srinivas Nandkumar, Ph.D.
Acting 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)*
K191634

Device Name
Scan Abutments and Comfort Caps

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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Dentium

510(k) Summary

06/10/2019

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	Byungsun Kim / RA bskim@dentium.com
Summary Date	06/10/2019

2. Device Name

Proprietary name	:	Scan Abutments and Comfort Caps
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 for Scan Abutment

K172640 Dentium Implantium® & SuperLine® Prosthetics

K153268 NR Line Implant System

Primary Predicate for Comfort Cap

K171142 Healing Cap Multi-Unit Titanium

Reference Devices

K173374	TSV BellaTek Encode Healing Abutments
K172160	Southern Implants PEEK Abutments

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 expand the Dentium Prosthetics to include the Scan Abutments and Comfort Caps.

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

Comfort Caps are used provisionally as an accessory to protect the dental abutment before final prosthesis.

They have the design feature that enable to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner.

The Scan Abutments and Comfort Caps are prefabricated and made of Ti-6Al-4V ELI (ASTM F136) or PEEK(ASTM F2026). Scan Abutments are compatible with Dentium Implant(k041368 Implantium and k160965 SuperLine or K153268 NR Line) and Comfort Caps are compatible with Dentium Prosthetics(K052957 Implantium and K172640 SuperLine or K153268 NR Line)

6. Performance Data

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

• Steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10^{-6}.

• Biocompatibility of Ti-6Al-4V ELI (ASTM F136) demonstrated by the referenced Dentium submission, K172640, using the same materials and manufacturing processes as the subject device.

And cytotoxicity testing of PEEK (ASTM F2026) has been performed according to ISO 10993-5.

No clinical data were included in this submission.

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 Scan Abutment - Implantium & SuperLine

Comparison of Characteristics

	Subject device	**Primary Predicate**	**Reference Predicate**	
Device name	Scan Abutment	Dentium Implantium® & SuperLine® Prosthetics (Healing Abutment)	TSV BellaTek Encode Healing Abutments	Southern Implants PEEK Abutments
Manufacturer	Dentium Co., Ltd.	Dentium Co., Ltd.	Biomet 3i	Southern Implants (Pty) Ltd
510(k) Number	New Device	K172640	K173374	K172160
Indication for use	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	The TSVTM BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Materials	Ti-4Al-6V ELI, PEEK	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	PEEK (ASTM F2026)
Form	Preformed	Preformed	Preformed	Preformed
Sterilization	Non-sterile	Non-sterile	Sterile	Sterile
Use	Prescription	Prescription	Prescription	Prescription
Single Use Only	Yes	Yes	Yes	Yes

Design				
Diameter	4.09 ~ 6.41mm	4.04 ~ 9.64 mm	3.8, 5.0, 5.6, 6.0, 6.8 mm	6 x 9, 8 x 11
Length	8.4 ~ 14.4 mm	8.89 ~ 14.51 mm	Gingival Height 3.0, 5.0, 7.0 mm	5.0 ~ 6.0 mm
Connection type	Internal	Internal	Internal	Internal
Scanning feature	Machined marking	-	Machined marking	-
Surface treatment	None	None	None	None

The subject device Scan Abutment is substantially equivalent to the predicate K172640(Healing Abutment) in indication for use, manufacture, function, design and implant/abutment interface.

The intended use of the subject device as a healing abutment with scanning feature machined marking to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner is equivalent to the reference predicate K173374.

The subject device is made of Ti-6Al-4V ELI (ASTM F136) or PEEK (ASTM F2026). Ti-6Al-4V ELI and PEEK are commonly used in endosseous dental implant abutments. The Ti-6Al-4V ELI is identical to the material used for Dentium components cleared previously in K172640 and PEEK is identical to the material cleared previously in K172160.

7.2 Scan Abutment - NR Line

Comparison of Characteristics

	Subject device	**Primary Predicate**	**Reference Predicate**	
Device name	Scan Abutment	NR Line Implant System (Healing Abutment)	TSV BellaTek Encode Healing Abutments	Southern Implants PEEK Abutments
Manufacturer	Dentium Co., Ltd.	Dentium Co., Ltd.	Biomet 3i	Southern Implants (Pty) Ltd
510(k) Number	New Device	K153268	K173374	K172160
Indication for use	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	The TSVTM BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in

			acceptance of a final abutment and restoration.	prosthetic rehabilitation.
Materials	Ti-4Al-6V ELI, PEEK	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	PEEK (ASTM F2026)
Form	Preformed	Preformed	Preformed	Preformed
Sterilization	Non-sterile	Non-sterile	Sterile	Sterile
Use	Prescription	Prescription	Prescription	Prescription
Single Use Only	Yes	Yes	Yes	Yes
Design				
Diameter	4.09 ~ 6.41mm	3.7 ~ 9.5 mm	3.8, 5.0, 5.6, 6.0, 6.8 mm	6 x 9, 8 x 11
Length	9.12 ~ 15.12 mm	8.6 ~ 12.1 mm	Gingival Height 3.0, 5.0, 7.0 mm	5.0 ~ 6.0 mm
Connection type	Internal	Internal	Internal	Internal
Surface treatment	None	None	None	None

The subject device Scan Abutment is substantially equivalent to the predicate K153268 (Healing Abutment) in indication for use, manufacture, function, design and implant/abutment interface.

The intended use of the subject device as a healing abutment with scanning feature machined marking to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner is equivalent to the reference predicate K173374.

The subject device is made of Ti-6Al-4V ELI (ASTM F136) or PEEK (ASTM F2026). Ti-6Al-4V ELI and PEEK are commonly used in endosseous dental implant abutments. The Ti-6Al-4V ELI is identical to the material used for Dentium components cleared previously in K153268 and PEEK is identical to the material cleared previously in K172160.

6.3 Comfort Cap

Comparison of Characteristics

	Subject device	**Primary Predicate**	**Reference Predicate**
Device name	Comfort Cap	Healing Cap Multi-Unit Titanium	Southern Implants PEEK Abutments
Manufacturer	Dentium Co., Ltd.	Nobel Biocare AB	Southern Implants (Pty) Ltd
510(k) Number	New Device	K171142	K172160
Indication for	Dentium Prosthetics are	The Healing Cap Multi-unit	The Southern Implants

use	intended for use as an aid in prosthetic rehabilitation.	Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.	PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Materials	Ti-4Al-6V ELI, PEEK	Ti-6Al-4V ELI (ASTM F136)	PEEK (ASTM F2026)
Form	Preformed	Preformed	Preformed
Sterilization	Non-sterile	Sterile	Sterile
Use	Prescription	Prescription	Prescription
Single Use Only	Yes	Yes	Yes
Design			
Diameter	4.5, 5.0, 5.5 mm	5.0, 6.0, 6.9 mm	6 x 9, 8 x 11
Length	5.0 mm	4.1, 5.5 mm	5.0 ~ 6.0 mm
Surface treatment	None	None	None

The subject device Comfort Cap is substantially equivalent to the predicate K171142 in indication for use, manufacture, function and design. The intended use of subject and predicate device is to protect the dental abutment before final prosthesis.

The subject device is made of Ti-6Al-4V ELI (ASTM F136) or PEEK (ASTM F2026). Ti-6Al-4V ELI and PEEK are commonly used in endosseous dental implant abutments. The Ti-6Al-4V ELI is identical to the material cleared previously in K171142 and PEEK is identical to the material cleared previously in K172160.

8. Conclusion

The subject device and the primary predicate device have the same indication for use, have similar technological characteristics, and are made of same materials. The subject device and primary predicate device encompass the equivalent range of physical dimensions, including diameter and length.