January 13, 2021

BEGO Implant Systems GmbH & Co. KG
Bertrand Lecointe
Regulatory Affairs Manager
Wilhelm-Herbst-Str. 1
Bremen, Bremen 28359
GERMANY

Re: K201700
Trade/Device Name: BEGO Semados® RS/RSX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 11, 2020
Received: December 14, 2020

Dear Bertrand Lecointe:

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 Steen
Assistant 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)*
K201700

Device Name
BEGO Semados® RS/RSX Implant System

Indications for Use *(Describe)*
The BEGO Semados® RS/RSX Implant System consists of implants, healing posts and abutments.

The BEGO Semados® RS/RSX implant is indicated for single or multiple unit restorations on splinted or non-splinted applications both in the upper and lower jaw. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading, depending on sufficient primary stability and appropriate occlusal loading.
The BEGO Semados® RS/RSX implant 3.0 is only indicated for single unit restorations of the lower lateral, central incisors or upper lateral incisors.
The healing posts are indicated for patients treated with BEGO Semados® RS/RSX implants for the time during healing of the surrounding soft tissue.
The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation.
PS ITA, PS TTiA and PS TTiA NH are intended to be used for a maximum period of 6 months.

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

Device Name: BEGO Semados® RS/RSX Implant System

1. Submitter information

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5. Date prepared

1/13/2021

6. Device identification

Trade/Proprietary name: BEGO Semados® RS/RSX Implant System
Classification name: Endosseous dental implant (21 CFR 872.3640)
Endosseous dental implant abutment (21 CFR 872.3630)
Primary product code: DZE
Secondary product code: NHA
Device class: Class II
Classification panel: Dental

7. Legally marketed predicate devices

Table 5A – List of devices chosen from the primary predicate devices

510(k) number of primary predicate device: K142260 Device name: NobelActive		
Trade name of the subject device	**Trade name of the primary predicate device**	**Manufacturer**
BEGO Semados® RS/RSX implants	NobelActive®	Nobel Biocare AB, SWEDEN
510(k) number of primary predicate device: K090716 Device name: BEGO Semados® S-Line		
Trade name of the subject device	**Trade name of the primary predicate device**	**Manufacturer**
PS HP and PS HPW	Healing posts	BEGO Implant Systems GmbH & Co. KG, GERMANY
PS TiA and PS TiAA	Sub-Tec Titanium abutment anatomical	

Table 5B – List of devices chosen from the reference predicate devices

510(k) number of reference predicate device: K090716 Device name: BEGO Semados® S-Line		
Trade name of the subject device	**Trade name of the reference predicate device**	**Manufacturer**
BEGO Semados® RS/RSX implants	BEGO Semados® S implant	BEGO Implant Systems GmbH & Co. KG, GERMANY
510(k) number of reference predicate device: K161435 Device name: Temporary Snap Abutment		
Trade name of the subject device	**Trade name of the reference predicate device**	**Manufacturer**
PS TTiA and PS TTiA NH	Temporary Snap Abutment	Nobel Biocare AB, SWEDEN
510(k) number of reference predicate device: K102436 Device name: NobelActive 3.0		
Trade name of the subject device	**Trade name of the reference predicate device**	**Manufacturer**
PS HP and PS HPW	Healing Abutments	Nobel Biocare AB, SWEDEN
PS ITA	Immediate Temporary Abutment	
PS TiA and PS TiAA	Esthetic Abutments and 15° Esthetic Abutment	
510(k) number of reference predicate device: K161416 Device name: Multi-unit Abutment Plus		
Trade name of the subject device	**Trade name of the reference predicate device**	**Manufacturer**
MultiPlus system	Multi-unit Abutment Plus	Nobel Biocare AB, SWEDEN
510(k) number of reference predicate device: K072878 Device name: Modification To Locator Implant Anchor		
Trade name of the subject device	**Trade name of the reference predicate device**	**Manufacturer**
Easy-Con system	Locator® Implant Anchor Abutment for Endosseous Dental Implant	ZEST Anchors Inc., USA

8. Device description

RS/RSX implants

BEGO Semados® RS/RSX implants (DZE - 872.3640 – Class II) are dental implants which are made for subgingival placement in both, the upper and lower jaw, using one- or two-stage surgical procedures. They are used to replace lost teeth and to attach prosthetic restorations.

BEGO Semados® RS/RSX implants are self-tapping, conical endosseous dental implants made of commercially pure titanium Grade 4 (ISO 5832-2 and ASTM F-67 compliant). In contrast to the RSX implant family, the RS implant family has a 0.5 mm machined neck region.

BEGO Semados® RS/RSX implants are marketed together with cover screws and insertion posts. BEGO Semados® Implant Cover Screws are intended for implant-abutment interface closure for submerged healing of the dental implant during a two stage surgical procedure. The insertion posts are used together with a ratchet or hand-piece to insert the implant.

Healing posts

The healing posts are sterile packaged Titanium Grade 5 (Ti6Al4V) (ISO 5832-3 and ASTM F-136 compliant) dental healing abutments that are available in two different types and different sizes. Healing posts can be used either to shape the soft tissue after sub-merged healing of an implant (two-stage) or to keep the shape of the soft tissue after having placed the implant (one-stage). The sizes are according to the sizes of the compatible BEGO Semados® implant. The following devices are included:

a) PS HP (Healing post Platform Switch);
b) PS HPW (Healing post wide body Platform Switch).

Abutments

The abutments are prefabricated prosthetic components made of Titanium Grade 5 (Ti6Al4V) (ISO 5832-3 and ASTM F-136 compliant) directly connected to BEGO Semados® implants with Platform Switch design such as BEGO Semados® RS/RSX implants. They are delivered non-sterile but have to be sterilized by the end-user They serve as an aid in temporary (provisional) and permanent prosthetic rehabilitation. The abutments are used for single or multiple tooth restorations. They are available in diameters compatible to the BEGO Semados® implant diameters (3.0-5.5mm). There are two types of abutments regarding the duration of use: provisional abutments intended for a limited period of ≤ six months and permanent abutments.

The abutments are marketed with the compatible prosthesis and a technician screw, which are identical in material composition, design and manufacturing process. The prosthesis screw is used to connect the abutment to the BEGO Semados® RS/RSX implant. The technician screw is used by the dental technician when making the prosthetic restoration.

For temporary (provisional) prosthetic restorations the following provisional abutments (temporary use, ≤ six months) are available:

a) PS TTiA (Provisional abutment Platform Switch);
b) PS TTiA NH (Provisional abutment Platform Switch);
c) PS ITA (Provisional abutment Platform Switch).

For permanent prosthetic restorations the following abutments are available:

a) PS TiA (Solid abutment titanium Platform Switch);
b) PS TiAA (Solid abutment titanium Platform Switch).

Multi^{Plus} system

The Multi^{Plus} system consists of the PS MultiPlus abutments, the MultiPlus Titanium abutment, the MultiPlus Healing posts, the MULTI PLUS UNIVERSAL component and various supporting tools like e.g. positioning aids.

The Multi^{Plus} system is intended for occlusal screw-retained bridge, full dentures and bar constructions in the mandible and maxilla.

a) PS MultiPlus abutments

The PS MultiPlus abutments are made of Titanium Grade 5 (Ti6Al4V) (ISO 5832-3 and ASTM F-136 compliant) and are screwed directly into the RS/RSX implants. They are available in two different gingiva heights (GH 1 mm and 3 mm) and in three different angulations (0°, 20° and 30°). PS MultiPlus abutments are delivered sterile with Multi^{Plus} positioning aid and prosthesis screw (20° and 30°).

b) MultiPlus Titanium abutment

The MultiPlus Titanium abutment is used for creating temporary and definitive constructions and is screwed onto the PS MultiPlus abutment (0°, 20° or 30°). The MultiPlus Titanium abutment is made of Titanium Grade 5 (Ti6Al4V) (ISO 5832-3 and ASTM F-136 compliant) and delivered sterile together with a prosthetic screw and a technician screw also made of Titanium Grade 5.

c) MULTI PLUS UNIVERSAL

MULTI PLUS UNIVERSAL is an abutment made of Polyoxomethylene (POM) which can be used for temporary and definitive constructions. It is casted by the technician with an alloy. MULTI PLUS UNIVERSAL is screwed onto the PS MultiPlus abutment (0°, 20° or 30°). It is delivered non-sterile together with a prothetic and a technician screw made of Titanium alloy grade 5 (ISO 5832-3 and ASTM F-136 compliant).

d) MultiPlus Healing posts

MultiPlus Healing posts are used for shaping the soft tissue after the osseointegration. They are made of Titanium grade 5 (ISO 5832-3 and ASTM F-136 compliant). MultiPlus Healing posts are delivered sterile.

Easy-Con System

The Easy-Con system consists of the PS Easy-Con abutment and the Easy-Con laboratory set.

a) PS Easy-Con abutments

PS Easy-Con abutments are prefabricated abutments which are used to retain full supported dentures in the mandible or maxilla on two to four implants. The PS Easy-Con abutment is made of Titanium alloy Ti-6Al-4V grade 5, according to ASTM F136 and coated with titanium nitride. It is delivered non-sterile.

b) Easy-Con laboratory set

The Easy-Con laboratory set consists of two Easy-Con retention caps which are made of Titanium alloy Ti-6Al-4V grade 5, according to ASTM F136 and two Easy-Con block-out rings which are made of Silicone. Furthermore the set contains two Easy-Con production inserts (black) and two sets of Easy-Con retention inserts (transparent, pink and blue).

c) Easy-Con retention inserts

The Easy-Con retention inserts are prefabricated components that are used exclusively in conjunction with the Easy-Con retention cap for prosthesis anchorage. The different colored retention inserts differ in the withdrawal force and the possible divergence compensation. All retention inserts are made of nylon.

9. Indications for use

The BEGO Semados® RS/RSX Implant System consists of implants, healing posts and abutments.

The BEGO Semados® RS/RSX implant is indicated for single or multiple unit restorations on splinted or non-splinted applications both in the upper and lower jaw. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading, depending on sufficient primary stability and appropriate occlusal loading.

The BEGO Semados® RS/RSX implant 3.0 is only indicated for single unit restorations of the lower lateral, central incisors or upper lateral incisors.

The healing posts are indicated for patients treated with BEGO Semados® RS/RSX implants for the time during healing of the surrounding soft tissue.

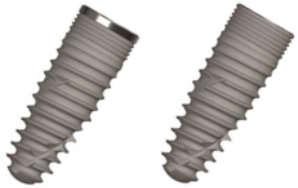
The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation.

PS ITA, PS TTiA and PS TTiA NH are intended to be used for a maximum period of 6 months.

10. Substantial equivalence discussion

The following tables compare the components of the BEGO Semados® RS/RSX Implant System to the predicate devices with respect to indications for use, intended use/principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject devices do not raise any new issues of safety or effectiveness based on the similarities to the predicate devices.

Table 5C – Comparison of characteristics for BEGO Semados® RS/RSX implants

	Subject device	**Primary predicate device (K142260)**	**Reference predicate device (K090716)**	**Comparison**
Trade Name	BEGO Semados® RS/RSX implants	NobelActive®	BEGO Semados® S implant	
Picture	 RS RSX			N/A
Indications for use	The BEGO Semados® RS/RSX implant is indicated for single or multiple unit restorations on splinted or non-splinted applications both in the upper and lower jaw. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading, depending on sufficient primary stability and appropriate occlusal loading. The BEGO Semados® RS/RSX implant 3.0 is only indicated for single unit restorations of the lower lateral, central incisors or upper lateral incisors.	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	The BEGO Semados® S-line threaded endosseous dental implants are indicated for restorations in the upper and lower jaw (single tooth replacement, abutments for bridgework, partial or complete edentulism).	Similar to primary predicate device, both are indicated for single or multiple prosthesis of partially or completely edentulous jaws. Both are intended for surgical placement in upper or lower jaw. Similar to primary predicate device, both include 3.0 diameter implants.

	Subject device	**Primary predicate device (K142260)**	**Reference predicate device (K090716)**	**Comparison**
Trade Name	BEGO Semados® RS/RSX implants	NobelActive®	BEGO Semados® S implant	
Implant type	Root form endosseous dental implant	Root form endosseous dental implant	Root form endosseous dental implant	Same
Anatomical location	Lower and upper jaw	Lower and upper jaw	Lower and upper jaw	Same
Placement method	One- or two-stage surgical procedure	One- or two-stage surgical procedure	One- or two-stage surgical procedure	Same
Clinical indication	Single or multiple unit restorations 3.0 mm for single unit restorations only	Single or multiple unit restorations 3.0 mm for single unit restorations only	Single or multiple unit restorations	Same
Single-use	Single use only	Single use only	Single use only	Same
Implant diameters (Ø) and lengths (L) [mm]	Ø 3.0: L10, L11.5, L13 Ø 3.75: L8.5, L10, L11.5, L13, L15 Ø 4.1: L7, L8.5, L10, L11.5, L13, L15 Ø 4.5: L7, L8.5, L10, L11.5, L13, L15 Ø 5.5: L7, L8.5, L10, L11.5, L13	Ø 3.0: L10, L11.5, L13, L15 Ø 3.5: L8.5, L10, L11.5, L13, L15, L18 Ø 4.3: L8.5, L10, L11.5, L13, L15, L18 Ø 5.0: L8.5, L10, L11.5, L13, L15, L18 Ø5.5: 7.0, 8.5, 10, 11.5, 13.0, 15.0	Ø 3.25: L8.5, L10, L11.5, L13, L15 Ø 3.75: L8.5, L10, L11.5, L13, L15 Ø 4.1: L7, L8.5, L10, L11.5, L13, L15 Ø 4.5: L8.5, L10, L11.5, L13, L15 Ø 5.5: L8.5, L10, L11.5, L13	Similar, all diameters and lengths are within the range of the predicate devices.
Endosseous implant material	Commercially Pure Titanium Grade 4 acc. to ASTM F67, ISO 5832-2	Commercially Pure Titanium Grade 4 acc. to ASTM F67, ISO 5832-2	Commercially Pure Titanium Grade 4 acc. to ASTM F67, ISO 5832-2	Same

	Subject device	**Primary predicate device (K142260)**	**Reference predicate device (K090716)**	**Comparison**
Trade Name	BEGO Semados® RS/RSX implants	NobelActive®	BEGO Semados® S implant	
Implant accessories	Cover screws 3.0-5.5 mm made of Titanium Grade 4 Insertion post 3.0-5.5 mm made of Titanium Grade 5	Cover Screws 3.0-5.5 mm made of titanium alloy TI-6AI-4V (Grade 5) No insertion posts included	Cover screws 3.25-5.5 mm made of Titanium Grade 4 Insertion post 3.25-5.5 mm made of Titanium Grade 5	Similar, except for the insertion posts and the material supported by a reference predicate device BEGO Semados® S implant.
Design	Self-tapping dental implant with internal hex connection	Self-tapping dental implant with Internal hex connection	Self-tapping dental implant with internal hex connection	Same
Implant shape	Straight/ parallel (upper part) Tapered (lower part)	Straight/parallel (upper part) Tapered (lower part)	Straight/ parallel (upper part) Tapered (lower part)	Same
Thread design	Self-tapping Two circular cutting edges in the apical and central region Thread depth of 0.35 mm to 0.49 mm in the conical part	Self-tapping , two circular cutting grooves in the lower part Reverse cutting flutes	Self-tapping Four ship spaces and cutting edges in the apical region Thread depth of 0.35 mm to 0.49 mm in the conical part	Similar

	Subject device	**Primary predicate device (K142260)**	**Reference predicate device (K090716)**	**Comparison**
Trade Name	BEGO Semados® RS/RSX implants	NobelActive®	BEGO Semados® S implant	
Implant-to-abutment connection	Conical (45° taper) connection Anti-rotation protection (Internal Hexagon) Platform Switch	Conical-tapered connection Anti-rotation protection (internal Hexagon) Platform Switch	Conical (45° taper) connection Anti-rotation protection (Internal Hexagon) Platform Match	Same/ Similar
Surface	TiPure^{Plus} microstructure	TiUnite (titanium oxide, anodized)	TiPure^{Plus} microstructure	Different but supported by the same surface of the reference predicate device
Surface treatment	Sandblasted and etched	Electrochemically modified	Sandblasted and etched	Different but supported by the same surface treatment of the reference predicate device

Table 5D – Comparison of characteristics for PS HP and PS HPW

	Subject device	**Primary predicate device (K090716)**	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS HP and PS HPW	Healing posts	Healing Abutments	
Picture	 PS HP PS HPW			N/A
Indications for use	The healing posts are indicated for patients treated with BEGO Semados® RS/RSX implants for the time during healing of the surrounding soft tissue.	The healing posts are indicated for patients treated with BEGO Semados® S implants for the time during healing of the surrounding soft tissue.	The Healing Abutments are premanufactured prosthetic components to be directly connected to the endosseous dental implants and are indicated as temporary components for one single tooth to full arch denture procedures.	Similar
Single use only	Yes	Yes	Yes	Same
Size (diameter and gingiva height)	PS HP: Ø 3.0, 4.0, 4.5, 5.0, 5.5, 6.5 mm with gingiva heights of 3, 5 and 7 mm (available for all diameters) PS HPW: Ø 5.5, 6.0, 6.5, 7.0 with gingiva heights of 3, 5 and 7mm (available for all diameters)	Ø 4.0, 4.5, 5.0, 6.0 mm with gingiva heights of 3, 5 and 7 mm (available for all diameters)	Ø 3.2 and 3.8 mm with gingiva heights 3, 5 and 7 mm (available for all diameters)	Similar, additional diameter for the 3.0 implant, broader range of diameters due to individual soft tissue situations
Healing post material	Titanium Grade 5 (Ti6Al4V) ASTM F136 ISO 5832-3	Titanium Grade 5 (Ti6Al4V) ASTM F136 ISO 5832-3	Titanium alloy Ti6Al4V	Same

	Subject device	**Primary predicate device (K090716)**	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS HP and PS HPW	Healing posts	Healing Abutments	
Healing post design	Soft tissue management (upper part) Tapered (lower part)	Soft tissue management (upper part) Tapered (lower part)	Soft tissue management (upper part) Tapered (lower part)	Same
Implant-to-Healing post connection	Conical (45° taper) connection, without rotation protection (cylinder)	Conical (45° taper) connection, without rotation protection (cylinder)	Conical connection, without rotation protection (cylinder)	Same

Table 5E – Comparison of characteristics for PS TTiA and PS TTiA NH

	Subject device	**Reference predicate device (K161435)**	**Comparison**
Trade name	PS TTiA and PS TTiA NH	Temporary Snap Abutment	
Picture			N/A
Indications for use	The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation. PS TTiA and PS TTiA NH are intended to be used for a maximum period of 6 months.	The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.	Similar
Single use only	Yes	Yes	Same
Abutment interface and overall height	Abutment interface: 3.2, 3.7, 4.1, 5.1 mm Overall height: 12 mm	Abutment interface: 3.0, 3.4, 3.4, 4.4 mm Overall height: 8.5, 10, 12 mm	Similar, diameters are due to the compatible implants. Height of subject devices may be customized.
Abutment material	Titanium Grade 5 (Ti6Al4V) ASTM F136 ISO 5832-3	Abutments and screws – Titanium vanadium alloy (ASTM F1472, ASTM F136)	Similar, ASTM F1472 is a Ti6Al4V alloy
Abutment design	Straight with retentive grooves (upper part), tapered (lower part)	Straight with retentive grooves (upper part), tapered (lower part)	Same

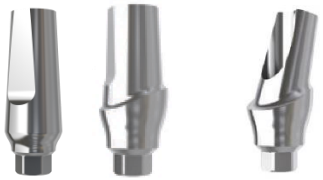
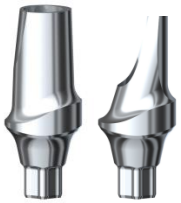
	Subject device	**Reference predicate device (K161435)**	**Comparison**
Trade name	PS TTiA and PS TTiA NH	Temporary Snap Abutment	
Implant-to-abutment connection	Conical (45° taper) connection PS TTiA: with anti-rotation protection (hexagon) PS TTiA NH: no-rotation protection (cylinder)	Internal Conical Connection with integrated snap feature, designed to facilitate prosthetic try in No-rotation protection (cylinder)	Similar, the basic geometry of the connection is equivalent.
Duration of use	≤ 6 month	180 days	Same

Table 5F – Comparison of characteristics for PS ITA

	Subject device	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS ITA	Immediate Temporary Abutment	
Picture			N/A
Indications for use	The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation. PS ITA are intended to be used for a maximum period of 6 months.	Immediate Temporary Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. Immediate Temporary Abutment Conical Connection 3.0 is indicated for use in the treatment of missing maxillary single lateral incisors or in the mandibular central and lateral incisors.	Similar, except for the time period. The subject device may only be used up to six months.
Single use only	Yes	Yes	Same
Abutment interface and overall height	Abutment interface: 2.6, 3.2, 3.7, 4.1 mm Abutment height: 7.1 mm	Abutment interface: 2.5, 3.0, 3.4, 3.4 Abutment height: 6.5, 8 mm	Similar, the labeling of the reference predicate device indicates that the device is available for all diameters of the compatible implant
Abutment material	Titanium Grade 5 (Ti6Al4V) ASTM F136, ISO 5832-3	Titanium vanadium alloy (ASTM F136)	Same

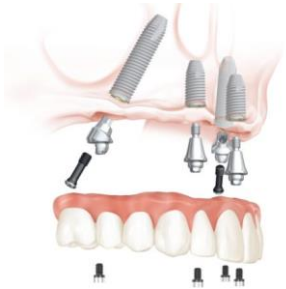
	Subject device	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS ITA	Immediate Temporary Abutment	
Abutment design	Straight (upper part), anatomically shaped (middle part), tapered with a cylinder and integrated connection screw (lower part)	Straight/parallel (upper part), tapered with integrated connection screw (lower part)	Similar, the reference predicate device has no anatomically shaped middle part
Implant-to-abutment connection	Conical (45° taper) connection, without rotation protection (cylinder)	Conical connection, without rotation protection (cylinder)	Similar, the basic geometry of the connection is equivalent.
Duration of use	≤ 6 month	Temporary without further specification	Similar, the subject device limits the use for six months.

Table 5G – Comparison of characteristics for PS TiA and PS TiAA

	Subject device	**Primary predicate device (K090716)**	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS TiA and PS TiAA	Sub-Tec Titanium abutment anatomical	Esthetic Abutment and 15° Esthetic Abutment	
Picture	 PS TiA PS TiAA			N/A
Indications for use	The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation.	Sub-Tec Titanium abutments anatomical are screwed directly into the implant and are used exclusively to make single tooth restorations / cement-retained restorations (crowns and bridges) due to their antirotation protection.	Esthetic Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. Esthetic Abutment Conical Connection 3.0 is indicated for use in the treatment of missing maxillary lateral incisors or in the mandibular central and lateral incisors.	Similar, the primary predicate device does not contain angulated abutments nor 3.0 mm diameter. The reference predicate device contains the angulated abutment for the diameter reduced implant.
Single use only	Yes	Yes	Yes	Same
Abutment interface and overall height	Abutment interface: 2.7, 3.2, 3.7, 4.1, 5.1 mm Gingiva height: 1-2 mm and 2.5-4 mm	Abutment interface: 3.75, 4.1, 4.5, 5.5 mm Gingiva height: 1-2 mm and 2.5-4 mm	Abutment interface: 2.5, 3.0, 3.4, 3.4, 4.4 mm	Similar, different abutment interfaces are due to the Platform Switch concept of the subject vs. Platform Match concept of the primary predicate device

	Subject device	**Primary predicate device (K090716)**	**Reference predicate device (K102436)**	**Comparison**
Trade name	PS TiA and PS TiAA	Sub-Tec Titanium abutment anatomical	Esthetic Abutment and 15° Esthetic Abutment	
Abutment angle	0°, 15°, 20°	0°	0°, 15°	Similar, the predicate devices do not contain 20° angled abutments
Abutment material	Titanium Grade 5 (Ti6Al4V) ASTM F136 ISO 5832-3	Titanium Grade 4 ASTM F67 ISO 5832-2	Titanium alloy Ti6Al4V	Similar, both materials are well-established because of their good biocompatibility performance
Abutment design	Straight or angled (upper part), different anatomical heights (middle part), tapered (lower part)	Straight (upper part), anatomical design (middle part), tapered (lower part)	Straight or angled (upper part), different anatomical heights (middle part), tapered (lower part)	Same
Implant-to-abutment connection	Conical (45° taper) connection, with anti-rotation protection (hexagon)	Conical (45° taper) connection, with anti-rotation protection (hexagon)	Conical connection, with anti-rotation protection (hexagon)	Same

Table 5H – Comparison of characteristics for MultiPlus system

	Subject device	**Reference predicate device (K161416)**	**Comparison**
Trade name	MultiPlus system	Multi Unit Abutment Plus	
Picture			N/A
Indications for use	The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation.	The Multi-unit Abutment Plus is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Similar
Single use only	Yes	Yes	Same
Abutment interface and overall height	Abutment interface: 3.2, 4.1, 4.5 mm Gingiva height: 0°: 1 and 3 mm 20°: 2.3-0.6 mm and 4.0-2.3 mm 30°: 4.0-1.5 mm	Abutment interface: 3.0, 3.4, 3.4, 4.4 mm Collar height: 1.5, 2.5, 3.5, 4.5 mm	Similar
Abutment angle	0°, 20°, 30°	0°, 17°, 30°	Similar
Abutment material	Titanium Grade 5 (Ti6Al4V) ASTM F136 ISO 5832-3	Titanium alloy Ti6Al4V	Same
Abutment design	Straight or angled (upper part), different anatomical heights (middle part), tapered (lower part)	Straight or angled (upper part), anatomical design (middle part), tapered (lower part)	Same

	Subject device	**Reference predicate device (K161416)**	**Comparison**
Trade name	MultiPlus system	Multi Unit Abutment Plus	
Implant-to-abutment connection	Conical connection 0°: no anti-rotation protection 20° and 30°: with anti-rotation protection (hexagon)	Conical connection	Same

Table 5I – Comparison of characteristics for Easy-Con system

	Subject device	**Reference predicate device (K072878)**	**Comparison**
Trade name	Easy-Con system	Locator® Implant Anchor Abutment for Endosseous Dental Implant	
Picture			N/A
Indications for use	The abutments are indicated for patients treated with BEGO Semados® RS/RSX implants as an aid in prosthetic rehabilitation.	The Locator® Implant Anchor Abutment for Endosseous Dental Implant is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.	Similar
Single use only	Yes	Yes	Same
Abutment interface and overall height	Abutment interface: 3.5-5.5 mm Gingiva height: 1, 2, 3 and 4 mm	Abutment interface: 2.5-6.5 mm Gingiva height: 1-6 mm	Similar, different abutment interfaces are due to the compatibility of the Locator System with the implant systems of various manufacturers
Abutment angle	0°	0°	Same
Material	Abutment: Titanium alloy Ti6Al4V Abutment coating: TiN Retention insert: nylon	Abutment: Ti6Al4V ELI Abutment coating: TiN Retention insert: nylon	Same

	Subject device	**Reference predicate device (K072878)**	**Comparison**
Trade name	Easy-Con system	Locator® Implant Anchor Abutment for Endosseous Dental Implant	
Abutment design	Straight (upper part) Different anatomical heights (middle part) Tapered (lower part)	Straight (upper part) Different anatomical heights (middle part) Tapered (lower part)	Same
Divergence allowance	≤ 40° between two implants with no more than 30° angulation per implant body	≤ 40° between two implants	Same
Prosthesis attachment type	Nylon Insert engaged to Denture Attachment Housing	Nylon Insert engaged to Denture Attachment Housing	Same
Implant-to-abutment connection	Conical, no rotation protection	Conical, External Hex, Internal Hex, Internal Multi Lobe	Similar

11. Non-clinical performance data

As part of demonstrating safety and effectiveness of BEGO Semados® RS/RSX Implant System, and in showing substantial equivalence to the predicate devices, BEGO Implant Systems GmbH & Co. KG completed a number of non-clinical performance tests. The BEGO Semados® RS/RSX Implant System meets all the requirements for overall design, sterilization, biocompatibility, and performance confirming that the design output meets the design inputs and specifications for the device.

The BEGO Semados® RS/RSX Implant System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject devices.

The materials were qualified according to ISO 5832-2:2018-03, ISO 5832-3:2016-10, ASTM F136-13 and ASTM F67-17 for Titanium Grade 4 and Titanium Grade 5 Material Specifications.

The biocompatibility was tested for contacting materials including cytotoxicity, sensitization and irritation reactivity per ISO 10993-5:2009-06 *"Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*" (XTT assay using mouse cell line L929 examined microscopically using phase contrast microscopy), ISO 10993-10:2010-08 "*Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"* (Test for delayed-type hypersensitivity Guinea pig maximization test) and ISO 10993-3:2014-10 "*Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*" (Ames reverse mutation assay: gene mutations in bacteria *Salmonella typhimurium)*.

A bacterial endotoxin testing was conducted for subject devices supplied as sterile according to USP 42-NF37 <85>, issued 2019.

The functional and mechanical properties were evaluated through physical testing:

- Static and dynamic fatigue tests were performed on BEGO Semados® RS/RSX implants in accordance with ISO 14801:2007-11 and ISO 14801:2016-11 *"Dentistry - Implants-Dynamic fatigue test for endosseous dental implants"* and the "*FDA guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments, issued March 12, 2004*" representing the most critical situation possible. BEGO Semados® RS/RSX implants were tested with PS TiA, PS TiAA and PS MultiPlus abutments;
- Energy disperse X-ray spectroscopy (EDX-analysis) and roughness test on surface were performed to evaluate the material composition at the implant surface level in line with ISO 4287:1997-04 "*Geometrical Product Specification (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters*" and ISO 4288:1996-08 "*Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture*".;
- Static immersion and open circuit potential measurements of BEGO dental abutments and BEGO Semados® RS/RSX implants have been conducted according to ISO 10271:2001-06 to determine the corrosion resistance.

A sterilization testing according to ISO 11137-2:2013-06 "*Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*", ISO 11737-1:2018-01 "*Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product*" and ISO 11737-2:2009-11 "*Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*" was conducted for

gamma-sterilized BEGO Semados® RS/RSX Implants, Implant Cover Screws, Healing posts PS HP and PS HPW, PS MultiPlus, MultiPlus Healing posts and MultiPlus Titanium abutment.

A sterility assurance level (SAL) of 10^{-6} was validated in accordance with ISO 11137-2:2013-06 "*Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*".

A sterilization validation according to ISO 17665-1:2006-08 "*Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*", and FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"* was conducted for end-user sterilized PS ITA, PS TTiA, PS TTiA NH, PS TiA, PS TiAA and PS Easy-Con, which are initially supplied as non-sterile.

A shelf life and transport packaging testing was conducted according to ISO 11607-1:2019-02 "*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*", ISO 11607-2:2019-02 "*Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*", ASTM F88/F88M-09 "Standard Test Method for Seal Strength of Flexible Barrier Materials" , ASTM F1886/F1886M-09 "*Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*", ASTM F1980-11 "*Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*", ASTM F1929-12 "*Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*", ASTM F2096-11 "*Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*", EN 868-5:2009 "*Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods*" and ISTA 2A:2011 "*Packaged-products 150 lb. (68 kg) or less*".

A usability engineering testing was conducted per IEC 62366-1:2015-02 "*Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]*", all requirements were met.

A risk management was assessed per ISO 14971:2007-03 "*Medical devices - Application of risk management to medical devices*", all requirements were met and risks reduced as far as possible.

A MR Safety investigation of BEGO Semados® implants and abutments was conducted and included a Displacement force test according to ASTM F2052-15, a Torque test according to ASTM F2213-06 (2011), a RF heating test according to ASTM F2182-11a and a MR image artefacts test according to ASTM F2119-07 (2013). It was demonstrated that BEGO Semados® implants and abutments are MR Conditional.

12. Clinical performance data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

13. Statement of substantial equivalence

Based on the information provided, the BEGO Semados® RS/RSX Implant System as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).