August 30, 2018

JJGC Indústria e Comércio de Materiais Dentários S.A.
℅ Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K180536
Trade/Device Name: Neodent Implant System - GM Line
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 6, 2018
Received: August 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180536

Device Name

Neodent Implant System – GM Line

Indications for Use *(Describe)*

Indications for Use for GM Helix Implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Exact Titanium Block for Medentika Holder:
GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Exact Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Titanium Base C for GM Exact abutments:
The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

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
K180536
Neodent Implant System – GM Line
JJGC Indústria e Comércio de Materiais Dentários SA

August 29, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 4000 Fax: +55 41 2169 4061
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System – GM Line
Common Name	Dental implant and abutment
Classification Name	Endosseous dental implant
Classification Regulation	21 CFR 872.3640
Device Class	Class II
Product Codes	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device is K163194.
The reference devices are K123022, K160964, and K150367.

INDICATIONS FOR USE

Indications for Use for GM Helix Implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Exact Titanium Block for Medentika Holder:
GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Exact Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Titanium Base C for GM Exact abutments:
The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations.
All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System – GM Line components cleared under K163194, which included dental implants with a Morse taper abutment interface (called Grand Morse, or GM), mating abutments, abutment screws, and other associated components. This submission includes: *GM Helix Implant* in diameter (6 mm), overall lengths of 8 mm to 13 mm, and in two endosseous surfaces, grit-blasted and acid etched (NeoPoros) and hydrophilic surface (Acqua); *GM Customizable Healing Abutment* in two prosthetic diameters (5.5 mm and 7.0 mm), each in multiple gingival heights (ranging from 1.5 mm to 6.5 mm); *GM Exact Titanium Block for Medentika Holder* titanium blank abutment, in two milling diameters, 11.5 mm and 15.8 mm; *GM Exact Titanium Base* in one prosthetic diameter (5.5 mm), six gingival heights (from 0.8 mm to 5.5 mm), and two prosthetic post heights (4 mm and 6 mm); and *Titanium Base C for GM Exact* one prosthetic diameter (4.65 mm), 6 gingival heights (from 0.8 mm to 5.5 mm), and one prosthetic post height (4.7 mm).

The *GM Exact Titanium Base* and *Titanium Base C for GM Exact* are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis; the *GM Exact Titanium Base* and *Titanium Base C for GM Exact* are two piece abutments used as a base when fabricating a CAD/CAM customized restoration. The *GM Exact Titanium Base* and *Titanium Base C for GM Exact* are provided in an anti-rotational shape for the coupling with the prosthesis and are available in diameters of 4.65 mm (*Titanium Base C for GM Exact*) and 5.5 mm (*GM Exact Titanium Base*), and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm. The planning and milling of the customized superstructures must be made using the validated Dental Wings Operating System (DWOS) or 3Shape software. All digitally designed copings and/or crowns for use with the *GM Exact Titanium Base* and *Titanium Base C for GM Exact* are intended to be manufactured at a validated milling center. The limits for customization are stated in the *GM Exact Titanium Base* and *Titanium Base C for GM Exact* product IFU. The superstructure produced through CAD/CAM System will compose the second part of the two-piece abutment; the assembly becomes a finished medical device after cementation on the *GM Exact Titanium*

Base or *Titanium Base C for GM Exact.* The *GM Exact Titanium Base* is indicated for screw-retained single-unit, or cement-retained single or multi-unit prosthesis attachment onto implants. The *Titanium Base C for GM Exact* is indicated for cement-retained single-unit prosthesis attachment onto implants.

The subject device abutments components mate exclusively with the GM implants cleared in K163194.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 11135, ISO 10993-7, ISO 17665-1, ISO 17665-2, and ISO 11135 10993-7 (referenced from K163194); bacterial endotoxin according to AAMI/ANSI ST72 (referenced from K163194); sterile barrier shelf life testing (accelerated aging according to ASTM F1980; seal integrity according to ASTM E499/E499M and ASTM F1929; seal strength according to ASTM F88/F88M; and sterility of the package contents according to ISO 11737, all referenced from K163194); biocompatibility (referenced from K163194); engineering analysis; dimensional analysis; and static and dynamic compression-bending according to ISO 14801. Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICES

JJGC Indústria e Comércio de Materiais Dentários S.A. submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate and reference devices:
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.;
K123022, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A.;
K160964, Neodent Implant System – Titanium Bases for CEREC, JJGC Indústria e Comércio de Materiais Dentários S.A.; and
K150367, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A.

A comparison of the Indications for Use statements for the subject device and the predicate and reference devices is provided in the following table.

Table of Substantial Equivalence – Indications for Use Statements

Comparison	Subject Device	Primary Predicate Device	Reference Devices		
	K180536	K163194	K123022	K160964	K150367
	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System – Titanium Bases for CEREC JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A
Indications for Use Statement	Indications for Use for GM Helix Implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for GM Exact Titanium Block for Medentika Holder: GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for GM Exact Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for Titanium Base C for GM Exact abutments: The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	Indications for Use for GM implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for GM Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for GM Pro Peek Abutments: The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Titamax WS implant is indicated for a delayed loading protocol. The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.	The Titanium Base for CEREC is a titanium component that is placed over Neodent Implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base for CEREC are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.

The Indications for Use Statement for the subject device (implants and conventional abutments section) is identical to the corresponding section of the Indications for Use Statement of the primary predicate device K163194. The Indications for Use Statement for the subject device (implants section) is identical to the corresponding section of the Indications for Use Statement of the reference device K123022. The Indications for Use Statement for the subject device (GM Exact Titanium Base abutments section) is identical to the corresponding section of the Indications for Use Statement of K163164 (GM Titanium Base abutments section), except for the names of the devices. The conventional abutments in this submission are the GM Customizable Healing Abutment. The subject device GM Exact Titanium Base abutments and Titanium Base C for GM Exact abutments are not considered conventional abutments. The slight differences in wording among the Indications for Use Statements for the subject device, K163194, and K123022 do not affect the intended use with dental implants for rehabilitation of the edentulous maxilla or mandible.

The Indications for Use Statement for the subject device (GM Exact Titanium Block for Medentika Holder section) is similar to the PreFace section of the Indications for Use Statement of the reference device K150367. The slight differences are the names of the devices (both are to be used with Medentika holder) and, for the subject device statement, the requirement to manufacture at a Straumann milling center. For K160367 the requirement to manufacture at a Straumann milling center was included in the labeling. The slight differences in wording between the Indications for Use Statements for the subject device and the reference device K150367 do not affect the intended use with dental implants for rehabilitation of the edentulous maxilla or mandible.

The Indications for Use Statement for the subject device (Titanium Base C for GM Exact abutments section) is similar to the Indications for Use Statement of the reference device K160964. The slight difference is the names of the devices. The slight differences in wording between the Indications for Use Statements for the subject device and the reference device K160964 do not affect the intended use with dental implants for rehabilitation of the edentulous maxilla or mandible.

A comparison of the technological characteristics of the subject device and the predicate and reference devices is provided in the following table.

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Devices		
	K180536	K163194	K123022	K160964	K150367
	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System – Titanium Bases for CEREC JJGC Indústria e Comércio de Materiais Dentários S.A.	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A
Reason for Predicate	Not applicable	Implant-abutment GM interface; Implant design; Healing Abutment design; Titanium Base designs	Implant design, 6 mm diameter	Titanium Base C design	Titanium Block (milling) design
Implants					
Implant Design	Threaded root-form implants, 1 thread design; Internal GM Morse taper connection (16°), with internal hex indexing feature (“Exact”)	Threaded root-form implants, 3 thread designs; Internal GM Morse taper connection(16°), with internal hex indexing feature (“Exact”)	Threaded root-form implants, 3 thread designs; Internal CM Morse taper connection(11.5°)		
Implant Diameter	GM Helix: 6.0 mm	GM Helix: 3.5, 3.75, 4.0, 4.3, 5.0 mm	Titamax WS implant: 4.0, 5.0, 6.0 mm		
Implant Length	GM Helix: 8, 10, 11.5, 13 mm	GM Helix: 8, 10, 11.5, 13, 16, 18 mm	Titamax WS implant: 5, 6 mm		
Material	Unalloyed titanium ASTM F67	Unalloyed titanium ASTM F67	Titamax WS implant: Unalloyed titanium ASTM F67		
Endosseous surface	NeoPoros (grit-blasted, acid-etched Acqua (NeoPoros + hydrophilic treatment)	NeoPoros (grit-blasted, acid-etched Acqua (NeoPoros + hydrophilic treatment)	NeoPoros (grit-blasted, acid-etched		
Abutments					
Healing Abutment	GM Customizable Healing Abutment	GM Pro PEEK Abutment			
Body (prosthetic) diameter	5.5 mm and 7.0 mm	4.5 mm and 6.0 mm			
Gingival height	5.5 mm Ø: 1.5, 2.5, 3.5, 4.5, 5.5 mm 7.0 mm Ø: 2.5, 3.5, 4.5, 5.5, 6.5 mm	4.5 mm Ø: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm 6.0 mm Ø: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm			
Material	Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)	Titanium alloy ASTM F136 (interface to implant) PEEK (customizable portion)			
Implant interface	Interfaces exclusively to Neodent GM implants	Interfaces exclusively to Neodent GM implants			
Titanium Block (milling)	GM Exact Titanium Block for Medentika Holder	GM Exact Click Universal Abutment 30°			PreFace
Body (milling) diameter	11.5 mm and 15.8 mm	n/a			11.5 mm and 15.8 mm
Abutment angle	15.8 mm Ø only: up to 30°	0°, 17°, 30°			15.8 mm Ø only: up to 30°
Prosthesis attachment	Screw-retained single-unit, or Cement-retained single or multi-unit	Cement-retained single-unit			Screw-retained single-unit, or Cement-retained single or multi-unit
Material	Titanium alloy ASTM F136	Titanium alloy ASTM F136			Titanium alloy ASTM F136

Comparison	Subject Device	Primary Predicate Device	Reference Devices		
	K180536	K163194	K123022	K160964	K150367
Implant interface	Interfaces exclusively to GM implants	Interfaces exclusively to GM implants			Interfaces exclusively to Neodent CM Morse taper implants
Titanium Base	GM Exact Titanium Base	GM Exact Titanium Base			Titanium Base
Body (prosthetic) diameter	5.5 mm	3.5 mm and 4.5 mm			3.5 mm and 4.5 mm
Abutment angle	Up to 30°	Up to 30°			Up to 30°
Gingival height	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm			0.8, 1.5, 2.5, 3.5, 4.5 mm
Prosthetic post height	4 mm and 6 mm	4 mm and 6 mm			4 mm
Prosthesis attachment	Screw-retained single-unit, or Cement-retained single or multi-unit	Cement-retained single-unit			Screw-retained single-unit, or Cement-retained single or multi-unit
Material	Titanium alloy ASTM F136	Titanium alloy ASTM F136			Titanium alloy ASTM F136
Implant interface	Interfaces exclusively to Neodent GM implants	Interfaces exclusively to Neodent GM implants			Interfaces exclusively to Neodent CM Morse taper implants (11.5° Morse taper)
Titanium Base	Titanium Base C for GM Exact	GM Exact Titanium Base		Titanium Base for CEREC	
Body (prosthetic) diameter	4.65 mm	3.5 mm and 4.5 mm		4.65 mm	
Abutment angle	Up to 20°	Up to 30°		Up to 30°	
Gingival height	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm		0.8, 1.5, 2.5, 3.5, 4.5, 5.5, 6.5 mm	
Prosthetic post height	4.7 mm	4 mm and 6 mm		4.7 mm	
Prosthesis attachment	Cement-retained single-unit	Cement-retained single-unit		Screw-retained single-unit	
Material	Titanium alloy ASTM F136	Titanium alloy ASTM F136		Titanium alloy ASTM F136	
Implant interface	Interfaces exclusively to Neodent GM implants	Interfaces exclusively to Neodent GM implants		Interfaces exclusively to Neodent CM Morse taper implants (11.5° Morse taper)	

The primary predicate device K163194 is for substantial equivalence of the subject device implants and the GM Morse taper abutment-implant interface design. All subject device abutments have the identical abutment-implant interface design as, and are to mate exclusively with, the Neodent GM implants cleared in K163194.

The subject device GM Helix implants are provided in the same design as the GM Helix implants cleared in K163194, with the exception of the additional 6 mm diameter. The reference device K123022 is for the 6 mm diameter size.

The subject device GM Customizable Healing Abutments are provided in the same abutment-implant interface design, gingival heights, and material as the GM Pro PEEK Abutments cleared in K163194. The subject device healing abutments and the GM Pro PEEK Abutments cleared in K163194 are both for temporary use and are not to be placed in occlusion; therefore, the larger prosthetic diameter of the subject device (7 mm) does not affect the substantial equivalence comparison to K163194.

The subject device GM Exact Titanium Block for Medentika Holder milling abutment is provided in the same design as the PreFace milling abutment cleared in K150367, except for the abutment-implant interface. The subject device mates exclusively with GM Morse taper implants; the PreFace device in K150367 mates exclusively with CM Morse taper implants. The limits of customization for the subject device GM Exact Titanium Block for Medentika Holder are identical to the GM Exact Click Universal Abutment 30°, which was cleared in K163194 and mates exclusively with GM Morse taper implants.

The subject device GM Exact Titanium Base abutments are provided in the same abutment-implant interface design, gingival heights, and material as the GM Exact Titanium Base abutments cleared in K163194. The subject device GM Exact Titanium Base abutments add a 5.5 mm prosthetic diameter. Therefore, the larger prosthetic diameter of the subject device does not create any additional risks or affect the substantial equivalence comparison to K163194. Mechanical testing according to ISO 14801 was provided to confirm the strength of the GM Exact Titanium Base abutment (5.5 mm diameter, 0.8 mm gingival height).

The subject device Titanium Base C for GM Exact abutments are provided in the same design as the Titanium Base for CEREC devices cleared in K160964, except for the abutment-implant interface. The subject device mates exclusively with GM Morse taper implants; the Titanium Base for CEREC device in K160964 mates exclusively with CM Morse taper implants. Engineering analysis was performed to demonstrate that the subject device Titanium Base C for GM Exact abutments (limited to 20° of angulation) are equivalent to the GM Exact Titanium Base in K163194 (limited to 30° of angulation). The subject device Titanium Base C for GM Exact abutments and the GM Exact Titanium Base cleared in K163194 mate exclusively with GM Morse taper implants.

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that the unalloyed titanium, titanium alloy, and PEEK materials used in the subject devices are identical in formulation, processing, component interactions, and storage conditions to the predicate devices in K163194.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing was performed according to ISO 14801 on worst-case subject device constructs. The results from the testing demonstrated fatigue performance of the subject device GM Exact Titanium Base to be substantially equivalent to that of the predicate device K163194.

The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above. Any differences in the technological characteristics between the subject and the predicate and reference devices do not raise different questions of safety or effectiveness.

CONCLUSION

The subject device and the predicate and reference devices have the same intended use, have similar technological characteristics, and are made of the same or similar materials. The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.