December 12, 2025

JJGC Indústria e Comércio de Materiais Dentários S.A.
℅ Jennifer Jackson
Sr. Director, Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K252090
Trade/Device Name: Pterygoid Indication for GM Helix Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 12, 2025
Received: November 12, 2025

Dear Jennifer Jackson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252090

Device Name
Pterygoid Indication for GM Helix Implants

Indications for Use *(Describe)*

GM Helix Implant:
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. The GM Helix Implant System with 3.75 and 4.0 diameter and 18 mm length are indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Implants in the pterygoid indication should be used in splinted applications that utilize at least two implants.

GM Helix LG Implant:
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. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. The GM Helix LG Implant System is indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

GM Mini Conical Abutment 45°:
The Mini Conical Abutments 45° and 60° are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used with single stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

GM Mini Conical Abutment 45° Slim:
The Mini Conical Abutments 45° and 52° are indicated for surgical procedures in Zygomatic bones, making possible the rehabilitation with screw-retained abutments over the implant, thus restoring the chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used in one- or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly.

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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Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

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13. 510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810, USA Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários S.A (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023 Email: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Leticia Milani Senior Regulatory Affairs Analyst
Date of Submission:	December 12, 2025

Name of the Device

Trade Names:	Pterygoid Indication for GM Helix Implants
Common Name:	Pterygoid Indication for GM Helix Implants
Classification Name:	Implant, Endosseous, Root-Form
Regulation Number:	21 CFR 872.3640
Device Classification:	2
Product Code(s):	DZE; NHA
Classification Panel:	Dental

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

Predicate Device(s)

Primary Predicate:

- *K212785 – Blue Sky Bio Dental Implant System*

Reference Devices:

- *K163194 – Neodent Implant System – GM Line*
- *K190958 – Neodent Implant System*
- *K190718 – Neodent Implant System – GM Zygomatic Implant System*
- *K232099 - Neodent Implant System – GM Zygomatic Implant System*
- *K182620 – MRI Compatibility for Existing Neodent Implant System*

Device Description

This premarket notification seeks to expand the indications for use of the subject implants and abutments, in order to include anchorage in the pterygoid region. These devices were previously cleared under 510(k) K163194, K190958, K190718 and K232099 for the functional and esthetic oral rehabilitation of the upper or lower jaw in edentulous or partially edentulous patients. The proposed implants and abutments remain with the same design and features already cleared in the original submission.

Indications for Use

GM Helix Implant:
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. The GM Helix Implant System with 3.75 and 4.0 diameter and 18 mm length are indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Implants in the pterygoid indication should be used in splinted applications that utilize at least two implants.

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

GM Helix LG Implant:

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. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. The GM Helix LG Implant System is indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

GM Mini Conical Abutment 45°:

The Mini Conical Abutments 45° and 60°* are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used with single stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

GM Mini Conical Abutment 45° Slim:

The Mini Conical Abutments 45° and 52° are indicated for surgical procedures in Zygomatic bones, making possible the rehabilitation with screw-retained abutments over the implant, thus restoring the chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used in one- or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly.

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* The GM Mini Conical Abutment 60° was cleared for use with zygomatic implants in K203542.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the Table 1.

The purpose of this submission is addition of the pterygoid indication. The subject implants and abutments have equivalent indications for use statements to the primary predicate (K212785). Specifically, when used in the pterygoid region the devices are all indicated for multiple unit restorations in splinted applications that utilize at least two implants in cases of severe jaw resorption in order to restore patient esthetics and chewing function. The proposed implant diameters (3.75 and 4.0mm) and implant lengths (GM Helix Implant -18mm and GM Helix LG Implants - 20, 22.5 and 25mm) for use in the pterygoid region are consistent with those specified for use in the pterygoid region in K212785. Additionally, the abutments specified for use in the pterygoid region (GM Mini Conical Abutment 45° and GM Mini Conical Abutment 45° Slim) have an angulation of 45° consistent those specified for use in the pterygoid region in K212785. The subject Neodent devices were originally developed and cleared with separate indication for use statements, so each device type statement is modified to add the pterygoid indication.

This submission is focused on labeling, and no changes were made to the existing cleared device designs. Therefore, the existing device clearances are included as reference devices in Table 1 to support the device designs.

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

Table 1– Table of Substantial Equivalence for proposed devices.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
K Number	-	***K212785*** ***Blue Sky Bio Dental Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K190958*** ***Neodent Implant System***	***K232099*** ***GM Zygomatic Implant System***
Implant Indications for Use	GM Helix Implant: 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. The GM Helix Implant System with 3.75 and 4.0 diameter and 18 mm length are indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Implants in the pterygoid indication should be used in splinted applications that utilize at least two implants. GM Helix LG Implant: 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 The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. The GM Helix LG Implant System is indicated for surgical installation in the pterygoid region (upper jaw), for multiple unit restorations, when combined with 45° angulation abutment, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	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	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. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
K Number	-	***K212785*** ***Blue Sky Bio Dental Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K190958*** ***Neodent Implant System***	***K232099*** ***GM Zygomatic Implant System***
Abutment Indication for Use	GM Mini Conical Abutment 45°: The Mini Conical Abutments 45° and 60°[1] are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used with single stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. GM Mini Conical Abutment 45° Slim: The Mini Conical Abutments 45° and 52° are indicated for surgical procedures in Zygomatic bones, making possible the rehabilitation with screw-retained abutments over the implant, thus restoring the chewing function. The Mini Conical Abutments 45° are also indicated for use with Pterygoid implants in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. The Mini Conical Abutments may be used in one- or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly.				GM Mini Conical Abutment 52° and 45°: Product indicated for surgical procedures in zygomatic bones, making possible the rehabilitation with screw-retained abutments over the implant, thus restoring the chewing function. It may be used in one- or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly.
Material	Implant: Titanium grade 4 Abutment: Titanium alloy.	Implant: Titanium alloy.	Implant: Titanium grade 4 Abutment: Titanium alloy.	Implant: Titanium grade 4 Abutment: Titanium alloy.	Abutment: Titanium alloy.
Implant Abutment Connection	Grand Morse (GM)	Internal Hex	Grand Morse (GM)	Grand Morse (GM)	Grand Morse (GM)

[1] The GM Mini Conical Abutment 60° was cleared for use with zygomatic implants in K203542.

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
K Number	-	***K212785*** ***Blue Sky Bio Dental Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K190958*** ***Neodent Implant System***	***K232099*** ***GM Zygomatic Implant System***
Design	Threaded root-form implant with internal Grand Morse (GM) taper connection with internal hex.	Threaded root-form implant with internal hex taper connection.	Threaded root-form implant with internal Grand Morse (GM) taper connection with internal hex.	Threaded root-form implant with internal Grand Morse (GM) taper connection with internal hex.	
Implant Diameter	3.75 and 4.0 mm	3.7, 4.3 and 5.0 mm	3.75 and 4.0 mm	3.75 and 4.0 mm	
Implant Length	GM Helix Implant: 18mm GM Helix LG Implant:20; 22.5 and 25 mm	18[2]; 20; 22.5 and 25 mm[3]	8, 10; 11.5; 13; 16 and 18 mm	20; 22.5 and 25 mm	
Abutment Angle	45°	Straight, 12°; 17°; 24°; 30° and 45°(45° used with BIO MAX LONG in pterygoid placement only)	Straight, 17° and 30°	Straight, 17° and 30°	45° and 52°
Abutment Gingival Height	1.5 and 2.5 mm				1.5 and 2.5 mm
Implant Surface	Neoporos and Acqua.	Grit blasted and acid etched	Neoporos and Acqua.	Neoporos.	
Single use	Yes	Yes	Yes	Yes	Yes
Sterilization Method	Implant: Gamma Irradiation. Abutment: Ethylene Oxide	Gamma Irradiation.	Implant: Gamma Irradiation. Abutment: Ethylene Oxide	Implant: Gamma Irradiation. Abutment: Ethylene Oxide	Implant: Gamma Irradiation. Abutment: Ethylene Oxide

[2] Per GUDID entry for article IPJN3718 Pterygoid NP BlueSky Implant 3.7x18

[3] Per K212785 510(k) Summary equivalence table for the two-piece BIO LONG Implants

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
K Number	-	***K212785*** ***Blue Sky Bio Dental Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K190958*** ***Neodent Implant System***	***K232099*** ***GM Zygomatic Implant System***
Literature review to support pterygoid	Clinical literature was submitted in support of the subject implant placement in the pterygoid region and implant dimensions. Clinical literature detailed in clinical data section reported on implant diameters covering those of the subject devices (Ø3.3-4.2mm with lengths of 10-28mm) for pterygoid placement.	Clinical literature was submitted in support of the subject implant placement in the pterygoid region and implant dimensions. Clinical literature in the summary reported on implant diameters covering those of the subject devices (Ø3.5-5.0mm with lengths of 10-25mm) for pterygoid placement.			

Performance Testing

Bench Testing

Assessments regarding dynamic fatigue testing were conducted according to 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*" and ISO 14801 "*Dentistry — Implants — Dynamic loading test for endosseous dental implants*". For dynamic fatigue tests, the results demonstrated that in identical conditions, the subject devices exhibit a level of performance equal or better than the primary predicate device. Insertion tests were also performed and it could be proven that there is an adequate insertion torque in different bone classes when the implant is inserted according to the surgical procedure.

MRI Compatibility Testing

An assessment was made to demonstrate that the MR conditional labeling from K182620 is applicable to the subject devices, and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

Biocompatibility Testing

Assessments regarding biological compatibility were performed according to ISO 10993-1 and to the FDA Guidance document "*Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*".

Representative samples of the worst-case devices were subjected to the following:

• Biological Safety Assessment guided by ISO 10993-1.

• Chemical characterization was performed per ISO 10993-18.

• Cytotoxicity testing was performed per ISO 10993-5.

The subject devices are equivalent in material and manufacturing processes to the reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.

Sterilization validation

The proposed implants are sterilized by Gamma Irradiation, according to ISO 11137-1 and ISO 11137-2. A minimum Sterility Assurance Level (SAL) of 1 x 10-6 has been validated for the method. The proposed abutments are sterilized by Ethylene Oxide (EO), the method was validated to a sterility assurance level (SAL) of $1x10^{-6}$ in accordance with ISO 11135:2014, "Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices". EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals". The sterilization of the subject devices are identical to the sterilization already cleared for the reference devices.

Shelf Life

The expiration date of the devices was determined considering the integrity of the product and the packaging tests after shelf life testing. The types of packaging of the subject devices are identical to the packaging of the reference devices. The shelf life for the NeoPoros Implants is 5 years, while for the Acqua Implants it is 4 years, which is the same from the reference devices (K163194 and K190958). The shelf life for the abutments is 5 years, which is the same from reference devices (K190718 and K232099).

Clinical Literature

Clinical literature review was conducted to support the placement of long implants in the pterygoid region, combined with angled abutments (including 45°), for the oral rehabilitation of patients. Collected data showed that these implants exhibited high survival and success rate (88.2% to 100%), over follow-up periods up to 10 years. In addition, the subject devices are within the range of dimensions reported for pterygoid implants in the literature. Collectively, these characteristics, supported by clinical evidence and technological comparisons, demonstrate that the GM Helix and GM Helix LG Implants are safe, effective, and substantially equivalent to the predicate device and the devices cited in the literature for pterygomaxillary rehabilitation.

Traditional 510(k) Submission

Pterygoid Indication for GM Helix Implants

K252090

Article (LRS)	Implant Diameter	Implant Length	Implant Angulation	Abutment Angle	Comment	Reference
8	3.75 – 5 mm	6 – 20mm	Not stated	0°, 17° and 30°	A total of 189 patients were rehabilitated with complete fixed maxillary prostheses supported by 1.817 implants, and 356 of these implants placed in pterygomaxillary sites. In total, 314 of the 356 implants placed in pterygomaxillary sites were osseointegrated, corresponding to a cumulative survival rate of 88.2% after a mean follow-up period of 4.68 years. The authors concluded that implants in this anatomical site provide predictable posterior support and reduce the need for sinus augmentation or bone grafting procedures	Balshi, T.J, Wolfinger, G.J e Balshi, S.F. Analysis of 356 pterygomaxillary implants in edentulous arches for fixed prosthesis anchorage. Int. J. Oral Maxillofac. Implant. . 1999.
34	4mm	7 – 18 mm	Not stated	Not stated	This retrospective study evaluated 992 implants placed in the pterygomaxillary region, and reported a survival rate of 93.75% up to 10 years after loading. According to the authors, this outcome suggests that longer implants, which are more likely to engage both cortical plates of the pterygomaxillary region, may provide enhanced primary stability and improved long-term success.	Balshi, Thomas, Slauch, Robert e Balshi, Stephen F. Brånemark System Implant Lengths in the Pterygomaxillary Region: A Retrospective Comparison. Implant Dentistry. 2013.
35	3.75 – 4mm	18 – 20 mm	15°, 45° and 60°	0° and 17°	This retrospective study evaluated the success of pterygoid implants and associated prostheses in patients with an atrophic posterior maxilla. Implant and prosthesis success were considered main outcomes and were assessed for at least 36 months after implant loading. A total of 66 implants were placed in the pterygoid region and 172 implants in the anterior maxilla. Of the 66 pterygoid implants placed into function, 62 survived over the 36-month follow-up period, resulting in a success rate of 99% and mean bone loss of 1.21 mm. These authors' findings indicated that implant placement in the pterygoid region is a viable alternative for rehabilitation of the atrophic posterior maxilla, providing excellent stabilization for bone-anchored prostheses in both partially and completely edentulous patients.	Curi, Marcos Martins, Cardoso, Camila Lopes and Ribeiro, Karina de Cássia Braga. Retrospective Study of Pterygoid Implants in the Atrophic Posterior Maxilla:. The International journal of oral & maxillofacial implants. 2015.
39	3.75 – 4.2 mm	18 – 25mm	25° and 45°	8° – 40°	The study evaluated the success rates of implants placed in the pterygoid region and prostheses placed using the TTPHIL technique in the posterior atrophic maxilla. An analysis was conducted on 75 patients, and the findings suggest that implants placed using the TTPHIL demonstrate high survival rates (96.8%), minimal marginal bone loss, and reliable stability in the rehabilitation of patients with posterior maxillary atrophy over two years.	Nag, Venkat P. Ratna, et al. Minimally Invasive Reconstruction of Atrophic Maxilla Using Novel TTPHIL Technique - A Retrospective Evaluation of Pterygoid Implants and Prosthesis Success in 75 Patients. Dentistry: Advanced Research. 2022.
40	3.75 mm	20 mm	Not stated	45°	This case report describes a graftless approach for full-arch immediate maxillary rehabilitation using the TTPHIL technique. The mouth opening was assessed and found to be adequate for implant placement in the pterygoid region. This case report demonstrated that the TTPHIL technique is a clinically effective for full-arch	Nag, Venkat Ratna, et al. Tall and Tilted Pin Hole Immediately Loaded Implants (TTPHIL) Technique for Maxillary Arch Rehabilitation. International Journal of Research & Review. 2018.

					maxillary rehabilitation, particularly in cases with limited bone availability.	
42	3.75 – 4.2 mm	13 – 20 mm	60° to 90°	Not stated	This study evaluated the clinical outcomes of placing implants in pterygoid region with a more vertical inclination than the conventional 45°, measured relative to the maxillary (occlusal) plane, in a follow-up over 14 years. In total, 454 implants were placed in 392 patients, and 438 (96.5%) achieved successful osseointegration, while 16 (3.5%) failed. Thirteen of these failures occurred at stage-two surgery, before loading. Among the failed implants, seven occurred in men and eight in women; ten failures were in smokers (60%) and four in non-smokers (40%). Two implants fractured after five years of loading in a bruxism patient.	Rodríguez, Xavier, et al. Modified Surgical Protocol for Placing Implants in the Pterygomaxillary Region: Clinical and Radiologic Study of 454 Implants. The International Journal of Oral & Maxillofacial Implants. 2012.
45	Not stated	16 – 28 mm	Not stated	Not stated	This retrospective multicenter study aimed to evaluate the surgical and prosthetic success rates of pterygoid implants placed with a minimum insertion torque of 45 Ncm to support fixed partial or full-arch rehabilitations without cantilevers. A total of 92 pterygoid implants were placed in 56 patients and followed up for one year. The pterygoid 92 implants used in this study measured between 16 and 28 mm in length. The study reported a 100% surgical success rate, with all implants achieving a torque value equal to or greater than 45 Ncm. Overall, this retrospective study demonstrated that pterygoid implants provide a reliable treatment alternative for patients with severe posterior maxillary atrophy.	Tealdo, T., et al. A retrospective multicentric study of 56 patients treated with 92 pterygoid implants for partial/ full arch implant supported fixed rehabilitation: implant and prosthesis success rate. Eur j musculoskel dis. 2023.
46	4.0 mm	11.5 – 18 mm	72° to 80°	Not stated	This study investigated the 1-year survival and success rates of pterygoid implants and their corresponding prostheses in individuals with severe atrophy of the posterior maxilla who required a complete-arch, immediately loaded fixed prosthesis. The study included 15 participants, with a total of 27 implants placed in the pterygoid region, with final angulations of 25° to 40° relative to the maxillary plane. All prostheses remained stable, and all implants showed complete osseointegration without pain, radiolucency, or peri-implant pathology. Overall, both survival and success rates were 100% with 1 year of follow-up period, with no failures observed in either pterygoid or conventional implants.	Signorini, Luca, et al. Immediate fixed rehabilitation supported by pterygoid implants for participants with severe maxillary atrophy: 1-Year postloading results from a prospective cohort study. The journal of prosthetic dentistry. 2021.

Conclusion

The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices in terms of functional and mechanical properties, sterilization method, technological characteristics, design, indications for use and raw material.