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

October 31, 2023

Re: K232099
Trade/Device Name: Neodent Implant System - GM Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 4, 2023
Received: October 4, 2023

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.

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,

Andrew I. Steen -S

Andrew I. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232099

Device Name
Neodent Implant System - GM Zygomatic Implants System

Indications for Use *(Describe)*

Indications for Use for Zygoma-S GM Implant:
Zygomatic implants are indicated for intraoral surgical procedures in the zygoma region in cases of severe maxilla bone resorption, to restore the patient's chewing function and aesthetics. Zygomatic Implants may be used in one or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load.

Indications for Use for 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.

Indications for Use for Coping for Removable Prosthesis:
The product, when used with non-zygomatic implants, 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 multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted. When used with zygomatic implants, the product is indicated for surgical procedure only in upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used in two-stage procedures (delayed loading protocol) and for multiple unit restorations. 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.

510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (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 Senior Director of Regulatory Affairs and Quality, Straumann USA E-Mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	October 27, 2023
Preparer / Alternate Contact	Mariana Hartmann Regulatory Affairs Coordinator mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – GM Zygomatic Implant System
Common Name	Endosseous dental implant
Classification Name	Implant, Endosseous, Root-Form
Classification Regulations	21 CFR 872.3640, Class II
Product Code (s)	Primary: DZE Secondary: NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K190718, Neodent Implant System – Zygomatic Implants and Abutments, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Devices	K151909, Noris Medical - Zygomatic Dental Implant System
	K203542, Neodent Implant System – Mini Abutment 60°, JJGC Indústria e Comércio de Materiais Dentários S.A.
	K210356 - Noris Medical Dental Implants System, Noris Medical.
	K173902, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A
	K182620, MRI Compatibility for Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Indications for Use for Zygoma-S GM Implant:
Zygomatic implants are indicated for intraoral surgical procedures in the zygoma region in cases of severe maxilla bone resorption, to restore the patient's chewing function and aesthetics. Zygomatic Implants may be used in one or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load.

Indications for Use for 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.

Indications for Use for Coping for Removable Prosthesis:
The product, when used with non-zygomatic implants, 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 multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.
When used with zygomatic implants, the product is indicated for surgical procedure only in upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used in two-stage procedures (delayed loading protocol) and for multiple unit restorations. Multiple rehabilitations may be splinted rigidly.

SUBJECT DEVICE DESCRIPTIONS

The subject devices implants are single use devices, provided sterile by Gamma Radiation, made of commercially pure Titanium grade 4 (ASTM F67). The Zygomatic Implant is a long implant with a nominal diameter of 3.50 and 3.75mm, conical apex with rounded tip, 3 helical chambers, trapezoidal thread and GM prosthetic interface. The cervical portion in both models has Ø 4.3 mm. The length varies from 30 to 55 mm. Zygomatic Implants are intended to provide support for a fixed prosthesis in patients with severe atrophy in the maxillary region. They are extra-long to allow bone anchorage in the zygomatic bone. The subject implants consider the Zygoma Anatomy-Guided approach (ZAGA) for planning the surgical steps, being indicated for extrasinus and extra maxillary installation technique (ZAGA-4).

The subject abutments are single use devices, provided sterile by Ethylene Oxide, made of Titanium alloy (TI6AI4V-ELI). They are intermediate prosthetic components angled at 52 and 45 degrees with gingiva heights 1.5 and 2.5 mm, to be installed on the implant, offering a structure to support the screw-retained multiple prosthesis. The abutments present GM prosthetic interface and are available in the anti-rotational form in the implant to abutment interface, and rotational form in the abutment to prosthesis interface, presenting different transmucosal heights.

The subject coping is single use device, provided sterile by Ethylene Oxide, made of titanium alloy (Ti6Al4V-ELI). It presents a NEO torque interface for torque application. The subject device has diameter 4.80 mm and total height 4.60 mm. They are indicated for removable prostheses with fitting over Mini Conical Abutment installed in the maxilla or mandible and can be used in partial removable prostheses or over dentures. They are compatible with all previously cleared GM Mini Conical abutments.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

Table 1 - Technological Characteristic Comparison Table

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use	**Implants** Zygomatic implants are indicated for intraoral surgical procedures in the zygoma region in cases of severe maxilla bone resorption, to restore the patient's chewing function and aesthetics. Zygomatic Implants may be used in one or two-stage procedures, multiple unit restorations, and immediate loading when there is primary stability and adequate occlusal load.	**Implants** Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	**Implants** NORIS Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.			**Equivalent** The subject devices and the primary predicate devices have the same Indications for Use. There are some slight differences in wording between the Indications for Use Statements for the subject device and the primary predicate device that do not affect the intended use. Both devices are dental implants to be placed in the zygoma region in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
	Abutments 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.			**Abutments** The Mini Conical Abutments are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. It 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.		**Equivalent** The subject devices and the reference predicate devices (K203542) have the same Indications for Use for the Abutments. The slight differences in wording between the Indications for Use statements for the subject abutments and the reference device do not affect their intended use of restore chewing function in multi-unit restorations placed onto zygomatic bone. These text differences does not result in a change of the risk-based assessment, since there is no new risks or modification of existing risks already identified for both devices.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
	Abutment for removable Prosthesis (coping): The product, when used with non-zygomatic implants, 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 multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted. When used with zygomatic implants, the product is indicated for surgical procedure only in upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used in two-stage procedures (delayed loading protocol) and for multiple unit restorations. Multiple rehabilitations may be splinted rigidly.				**Abutment for removable Prosthesis:** 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.	**Equivalent** The subject devices and the reference predicate devices (K173902) have the same indications for use, being used to restore the chewing function. Some slight differences in the text can be observed as the indication for use of the subject copings is more specific to the product and does not correspond to all Neodent Implant System. This change was made to better clarify the application of the product according to the surgical situation, but is covered by the general indication for all system already presented for the reference predicate device.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Design	**Implants** Partially threaded root-form implant in the lower region to be used with matching abutments, made of Commercially Pure Titanium (Grade 4)	**Implants** Threaded root-form implant to be used with matching abutments, made of Commercially Pure Titanium (Grade 4)	**Implants** Partially threaded root-form implants for placement into the zygoma.			**Equivalent** The design of the subject device is very similar to the reference devices (K151909). Both are partially threaded implants. The primary predicate device is manufactured of the same raw material of the subject devices. The equivalence of the subject and reference device was evaluated by the comparison of performance in bench tests and is being further addressed in this submission.
	Abutment 45° and 52° angled abutments made of titanium alloy, intended exclusively for use with the GM Zygomatic implants. Gingival Height: 1.5; 2.5 mm Angulation: 45° and 52°	**Abutment** 45° angled abutments made of titanium alloy, intended exclusively for use with the GM Zygomatic implants. Gingival Height: 1.5; 2.5 mm Angulation: 45°	**Abutment** 45° angled abutments made of titanium alloy.	**Abutment** 60° angled abutments made of titanium alloy, intended for use with the GM Zygomatic implants. Gingival Height: 1.5; 2.5 mm Angulation: 60°		**Equivalent** The subject device gingival heights are identical to the primary and reference devices (K203542). The angulation of 45° is the same to the primary predicate devices (K190718) and the angulation of 52° is lower than the one of the reference predicate devices (K203542). Since the worst case configuration is the bigger angulation for the system, bench tests are being provided to prove equivalency between the subject devices and reference devices.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
	Abutment for removable Prosthesis (coping): Cylindrical abutment with GM interface. Made of Ti-6Al-4V alloy, ASTM F136, with TiN coating.				**Abutment for removable Prosthesis:** Cylindrical abutment with GM interface. Made of Ti-6Al-4V alloy, ASTM F136, with TiN coating.	**Identical** The overall design of the subject device and the reference device (K173902) are the same.
Reusable	No	No	No	No	No	**Identical** All subject devices and predicate devices are indicated for single use only.
Diameter (mm)	Endosseous diameter 3.5 and 3.75 Platform diameter 4.3	Endosseous diameter 4.0 Platform diameter 4.0	Endosseous diameter 4.2 Platform diameter 3.75			**Equivalent** Although the subject devices present some differences in the diameter size when compared to the primary and reference devices, bench tests were performed to show equivalency.
Length (mm) **(Implants)**	30; 35; 37.5; 40; 42.5; 45; 47.5; 50; 52.5; 55	30; 35; 37.5; 40; 42.5; 47.5; 50; 52.5; 55	35; 37.5; 40; 42.5; 47.5; 50; 52.5; 55; 57.5			**Equivalent** The subject devices range of lengths are similar to the primary and predicate devices lengths.
Implant surfaces	Sand blasted, acid etched NeoPoros surface in the thread region and smooth surface in the middle and upper regions.	Sand blasted, acid etched NeoPoros surface.	Partially threaded root-form implants for placement into the zygoma with unthread smooth surface in coronal portion.			**Equivalent** The subject devices and the primary predicate devices present the same implant surfaces (Neoporos) in the threaded region. The unthread smooth surface in upper region is equivalent of reference predicate device K151909.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151909** Zygomatic Dental Implant System Noris Medical	**K203542** Neodent Implant System - Mini Abutment 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Sterilization Method	**Implants** Gamma Radiation to an SAL of $1x10^{-6}$	**Implants** Gamma Radiation to an SAL of $1x10^{-6}$	**Implants** Gamma irradiation to an SAL of $1x10^{-6}$			**Identical** The subject devices and the primary predicate devices present the same Sterilization Methods.
	Abutments Ethylene Oxide to an SAL of $1x10^{-6}$	**Abutments** Ethylene Oxide to an SAL of $1x10^{-6}$		**Abutments** Ethylene Oxide to an SAL of $1x10^{-6}$	**Abutments** Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices present the same Sterilization Methods.

The subject device and the primary predicate device K190718 have the equivalent Indications for Use statements, similar designs, equivalent lengths, same surface treatment, same sterilization methods and same sterile barrier. The subject devices and the primary predicate device abutments present same range of gingival height, same raw material, same sterilization method and same sterile barrier.

The subject devices and the reference devices (K151909) have equivalent Indications for Use statements and similar design.

The subject abutments have the equivalent indications for use and same overall design as the reference devices (K293542 and 173902). They also present the same sterilization method and raw materials.

Overall, the subject devices are substantially equivalent to the predicate devices as follows:
• equivalent intended use,
• equivalent technological characteristics,
• equivalent design,
• same operating principle,
• incorporate the same materials, and
• have same packaging and are sterilized using the same materials and processes.

PERFORMANCE DATA

Performance Testing – Bench

Dynamic fatigue testing was 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". To comply with the indication for use in ZAGA-4, a deviation in the test configuration was made to better simulate the conditions of use of the devices, being the samples fixation adapted. The test was conducted in a dry environment (15 Hz and 20 ± 5°C) at 5 million cycles covering permanent restoration without implant failure. Results demonstrated the subject devices are equivalent to the reference devices being in compliance with the proposed indication for use.

Insertion tests were performed for the subject implants 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. Torsion Test was also performed to evaluate the strength of the subject device against maximum twisting forces when a rotational loading is applied. The results met the acceptance criteria.

The subject devices were also analyzed using scanning electron microscopy and light microscopy to investigate the apical end of the implant body after removal from the packaging. All the inspected implants showed a uniform breaking surface, with no residual metal fragments at the broken tip area.

Surface treatment

The subject implants have a rough surface in their apical region created by a sand-blasted and acid-etched treatment (Neoporos). This surface treatment is equivalent for all Neodent Implants with Neoporos surface, including the primary predicate device. The main difference in the surface treatment of the subject implants is in the cervical portion, which have a smooth machined surface since it does not receive any treatment, similar to the one presented in the reference device (K151909)

MR Compatibility testing

The MR compatibility was performed to access the risk of exposing patients who have implantable medical devices. An assessment was made to demonstrate that the subject devices are MR conditional devices and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

Sterilization validation

The subject implants are sterilized by Gamma Irradiation, according to ISO 11137-1 and ISO 11137-2, and the subject abutments by Ethylene Oxide, according to ISO 11135-1 via the over-kill method. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated for both methods. The subject devices are not represented to be “non-pyrogenic”.

Shelf Life validation

The expiration date of the products 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 primary predicate devices, including the implant packaging model with an apical pin connection. The shelf life for devices provided sterile is 5 years.

Biocompatibility

Representative samples of each of the subject devices was subjected to the following:

- Biocompatibility sample preparation was made according to ISO 10993-12;
- Biological Safety Assessment guided by ISO 10993-1;
- Cytotoxicity testing was performed per ISO 10993-5;
- Chemical characterization was performed per ISO 10993-18.

Clinical data

Clinical data from the published literature showed 971 smooth zygomatic implants marketed for the rehabilitation of 397 patients with severely resorbed maxillae, with high survival rates (93.3% to 100%) up to 11 years of follow-up. Overall, observed adverse events and complications described in the literature were implant failure, fracture of the zygomatic bone, infection, pain, inflammation, peri-implantitis, buccal abscess, sinusitis, mucositis, paresthesia, bone loss, plaque, bleeding, and soft tissue recession, osseointegration failure, prosthesis and abutment fracture, wrong prosthetic rehabilitation, zygomatic bone periostitis, overloading by the prosthetic over structure, oroantral sinus communications, prosthetic screw and abutment loosening, perforation of sinus membrane and cavity, tooth debonding, mucosal fenestration with no inflammation, slight intrusion movement and maxillary sinus opacity. The adverse events mentioned before are events already known for zygomatic implants in general.

Regarding the clinical outcomes of the predicate device, clinical articles from literature presented, in general, a total of 222 patients with 416 implants placed, mean of follow-up up to 41.75 months and survival rates of 93.3% to 100%. Implant loss, postoperative sinusitis, implant fracture, mucositis, paresthesia, zygomatic bone periostitis, inflammation with fistula, oroantral sinus communications, peri-implantitis were observed as complications.
Therefore, the clinical data evidence that the JJGC Zygoma-S GM Implants are safe and have an suitable performance if used according to the indications for use.

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.