April 28, 2020

JJGC Industria e Comercio de Materiais Dentarios S.A.
℅ Jennifer Jackson
Director of Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K193592
Trade/Device Name: Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 10, 2020
Received: April 13, 2020

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193592

Device Name
Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

Indications for Use *(Describe)*
- Neodent Implant System (originally cleared per K133592)

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. Multiple tooth applications may be rigidly splinted.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193592

Device Name
Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

Indications for Use *(Describe)*
- Neodent Implant System (originally cleared per K150182)

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.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K193592

Device Name
Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

Indications for Use *(Describe)*
- Neodent Implant System (originally cleared per K150199)

CM Alvim Acqua 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. Multiple tooth applications may be rigidly splinted.

Facility Acqua 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 Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.

CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic 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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193592

Device Name
Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

Indications for Use *(Describe)*
- Neodent Implant System - GM Line (originally cleared per K163194)

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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193592

Device Name
Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

Indications for Use *(Describe)*
- Neodent Implant System - GM Line (originally cleared per K180536)

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 cemented-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 cemented-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)

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Parana, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director of Regulatory Affairs, Straumann USA E-mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	28/Apr/2020
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name Acqua Implants	Neodent Implant System – Change in the Shelf Life for Neodent
Common Name	Endosseous dental implant
Classification Name	Implant, Endosseous, Root-Form
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Predicate Devices	K133592 – Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A;

K150182 – Neodent Implant System – CM Drive Implants, JJGC Indústria e Comércio de Materiais Dentários S.A;

K150199 – Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A;

K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A;

K180536, 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 K133592

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. Multiple tooth applications may be rigidly splinted.

Indications for Use K150182

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 K150199

CM Alvim Acqua 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. Multiple tooth applications may be rigidly splinted.

Facility Acqua 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 Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.

CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic 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 K163194

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.

Indications for Use K180536

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 cemented-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 cemented-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 DESCRIPTIONS

The present submission is for an increase in the shelf life of the implants of the Neodent Implant System having the Acqua surface treatment; the shelf life is being extended from 2-years to 4-years.

The subject devices are:

- Intended for single use;
- Provided sterile via gamma irradiation;
- Manufactured of commercially pure titanium grade 4;
- Root-form, threaded implants with Acqua surface treatment;
- Compatible with several implant-to-abutment interfaces of the Neodent Implant System as presented in the Comparison Tables below.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

Table 1. Comparative table between subject implants and previously cleared implants per K133592

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K133592** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use	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. Multiple tooth applications may be rigidly splinted.	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. Multiple tooth applications may be rigidly splinted.
Design	An external hex threaded root-form implant to be used with mating abutments having an integral anti-rotation feature.	An external hex threaded root-form implant to be used with mating abutments having an integral anti-rotation feature.
Reusable	No	No
Dimensions	**Titamax Ti EX Acqua and Titamax Smart EX Acqua:** Implant Ø: 3.75, 4.0 mm Length: 9, 11, 13, 15, 17 mm Platform Ø: 4.1 mm	**Titamax Ti EX Acqua and Titamax Smart EX Acqua:** Implant Ø: 3.75, 4.0 mm Length: 9, 11, 13, 15, 17 mm Platform Ø: 4.1 mm
	Drive Ti Acqua and Drive Smart Acqua: Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm Platform Ø: 3.3, 4.3, 5.0 mm	**Drive Ti Acqua and Drive Smart Acqua:** Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm Platform Ø: 3.3, 4.3, 5.0 mm
	Titamax CM EX Acqua: Implant Ø: 3.5, 3.75, 4.0mm Length: 9, 11, 13, 15, 17, 19 mm Platform Ø: 3.5, 3.75, 4.0mm	**Titamax CM EX Acqua:** Implant Ø: 3.5, 3.75, 4.0mm Length: 9, 11, 13, 15, 17, 19 mm Platform Ø: 3.5, 3.75, 4.0mm
	Drive CM Acqua: Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm Platform Ø: 3.5, 3.9 mm	**Drive CM Acqua:** Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm Platform Ø: 3.5, 3.9 mm
Material	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4
Sterilization Method	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.
Shelf Life	4 years	2 years

Table 2. Comparative table between subject implants and previously cleared implants per K150182

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150182** Neodent Implant System – CM Drive Implants JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use	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.
Design	An external hex threaded root-form implant to be used with mating abutments having an integral anti-rotation feature.	An external hex threaded root-form implant to be used with mating abutments having an integral anti-rotation feature.
Reusable	No	No
Dimensions	Implant Ø: 3.5, 4.3 and 5.0 mm Length: 18 mm Platform Ø: 3.5, 3.9 and 5.0 mm	Implant Ø: 3.5, 4.3 and 5.0 mm Length: 18 mm Platform Ø: 3.5, 3.9 and 5.0 mm
Material	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4
Sterilization Method	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.
Shelf Life	4 years	2 years

Table 3. Comparative table between subject implants and previously cleared implants per K150199

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150199** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use	CM Alvim Acqua 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. Multiple tooth applications may be rigidly splinted. Facility Acqua 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 Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures. CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic 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.	CM Alvim Acqua 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. Multiple tooth applications may be rigidly splinted. Facility Acqua 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 Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures. CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic 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.
Design	An indexed Morse taper threaded root-form implant to be used with mating abutments.	An indexed Morse taper threaded root-form implant to be used with mating abutments.
Reusable	No	No
Dimensions	Platform Ø: 3.5, 4.3, 5.0 mm Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm	Platform Ø: 3.5, 4.3, 5.0 mm Implant Ø: 3.5, 4.3, 5.0 mm Length: 8, 10, 11.5, 13, 16 mm
Material	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4
Sterilization Method	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.
Shelf Life	4 years	2 years

Table 4. Comparative table between subject implants and previously cleared implants per K163194

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use	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.	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.
Design	The dental implants are threaded, self-tapping, root form and present a Morse taper implant-to-abutment interface with an internal hexagonal index exclusive to the GM line.	The dental implants are threaded, self-tapping, root form and present a Morse taper implant-to-abutment interface with an internal hexagonal index exclusive to the GM line.
Reusable	No	No
Dimensions	Implant Ø: 3.5 to 5.0 mm Length: 8 to 18 mm	Implant Ø: 3.5 to 5.0 mm Length: 8 to 18 mm
Material	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4
Sterilization Method	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.
Shelf Life	4 years	2 years

Table 5. Comparative table between subject implants and previously cleared implants per K180536

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180536** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.
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 cemented-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 cemented-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 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 cemented-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 cemented-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.
Design	Threaded root-form implants, 1 thread design; Internal GM Morse taper connection (16°), with internal hex indexing feature (“Exact”)	Threaded root-form implants, 1 thread design; Internal GM Morse taper connection (16°), with internal hex indexing feature (“Exact”)
Reusable	No	No
Dimensions	Implant Ø: 6.0 mm Length: 8, 10, 11.5, 13, 16, 18 mm	Implant Ø: 6.0 mm Length: 8, 10, 11.5, 13, 16, 18 mm
Material	Commercially pure titanium, grade 4	Commercially pure titanium, grade 4

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	Neodent Implant System – Change in the Shelf Life for Neodent Acqua Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180536** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.
Sterilization Method	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.
Shelf Life	4 years	2 years

SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject devices and the predicate devices K133592, K150182, K150199, K163194 and K180536 have the same Indications for Use, same design, are manufactured using the same raw material and share the same sterilization method. The only change between them is the shelf life, which is the reason of this submission. The subject devices were originally cleared with a shelf life of 2 years. After a real-time aging study the company has determined that the shelf life of the implants can be extended to 4 years.

PERFORMANCE DATA

The tests performed to support the request for shelf life extension were the following:

- Product integrity after shelf life;
- Maintenance of hydrophilicity characteristics of the Acqua surface treatment after shelf life;
- Package integrity testing after shelf life;
- Biological safety of the product after shelf life.

The hydrophilicity presented a dynamic contact angle of 0° when the acceptance criteria is a dynamic contact of < 5°. The result is considered satisfactory.

The integrity of the sterile barrier and of the sealing were evaluated after Real Time Aging test. Verification tests were performed according to ASTM F88, ASTM F1929 and ASTM F2096. All the tests have demonstrated to be satisfactory for their intended uses.

Biological Safety Assessment was guided by ISO 10993-1.

Biocompatibility sample preparation was performed per ISO 10993-12.

Cytotoxicity was guided by ISO 10993-5. No cytotoxic effect was found under described extraction conditions.

The table below presents a summary of non-clinical evaluation performance.

Test	Standard/Reference	Acceptance Criteria	Result
Hydrophilicity (Dynamic Contact Angle)	Wilhelmy method (Gittens, et al., 2014)	Dynamic contact angle < 5	Passed
Visual Evaluation	N/A	No abrasion, rips, creases, detachment, or any other non-compliance that affect the packaging performance or the readability of the labeling information.	Passed
Dye Penetration	ASTM F1929	No dye solution leakage through the blister sealing.	Passed
Bubble Test	ASTM F2096	No constant flow of bubbles in the sealed area of the blister indicating a failure area.	Passed
Sealing Strength Test	ASTM F88	Present values of seal resistance between 1.5 N and 15 N for specimens with width of 15 ± 1 mm.	Passed
Cytotoxicity	ISO 10993-5	Inhibition of proliferation less than 30% compared to untreated cultures (reagent control)	Passed

CONCLUSION

The subject devices and the predicate devices have the same intended use, same designs and technological characteristics, same sterilization method and are made of the same materials. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.