July 14, 2023

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: K222026
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 14, 2023
Received: June 14, 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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

Andrew 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222026

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*
Indications for Use for Zirconia Bases:

The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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	July 13, 2023
Preparer / Alternate Contact	Mariana Hartmann Regulatory Affairs Leader E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – Zirconia Implant System
Common Name	Endosseous dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K201491 – Neodent Implant System – Zirconia Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A;
Reference Device	K142890 – Institut Straumann AG – Straumann® Variobase™ Abutments K163194 - Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A

K223638 - Neodent Implant System – Helix Short Implant System; JJGC Indústria e Comércio de Materiais Dentários S.A.

INDICATIONS FOR USE

Indications for Use Zirconia Bases:
The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

SUBJECT DEVICE DESCRIPTIONS

The Zirconia Base abutment is used as two-piece abutment, where the base is premanufactured from zirconia and the top half is created via burn out coping or a digital workflow with CAD/CAM at a validated milling center. The top half and base pieces are cemented together to form the final abutment

This submission aims to introduce the conventional workflow for obtaining prostheses manually designed by the technician using the Zirconia Bases, already cleared under K201491. With that, the introduction of one more restoration material (IPS e.max® Press) for the top half confection is necessary. The conventional workflow, using the IPS e.max® Press as restoration material along with the suggested cement materials is equivalent to the design workflow indicated for reference device (K142890). The table below details the restorative material introduced and the cement materials involved in the conventional workflow for the Zirconia Bases:

	Top Half Material	**Cement Material**
Material Name	IPS e.max® Press	Ivoclar Multilink
Raw Material	Lithium Dissilicate	Lithium Dissilicate
510(k)	K120053	K130436

The subject and primary predicate devices (K201491) have identical Indications for Use statements, providing the support for patient-specific prosthetic restorations. They also present the same raw material, technological characteristics (design and gingival height), reuse indication, sterilization method and sterile barrier.

Regarding the restoration material, focus of this submission, the IPS e.max® Press used to create the top half under the subject device are already cleared in the same configuration under K142890 (reference device). The Ivoclar Multilink cement material has also been previously cleared to be used together with IPS e.max restoration materials, under K223638 (reference device), with the intention to prepare a prosthetic restoration under implantable devices.

The results of the comparison between the subject, predicate and reference devices using the IPS e.max restoration materials along with the cement materials demonstrate that they are substantially equivalent.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System – Zirconia Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K201491** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K142890** Straumann® Variobase™ Abutments Institut Straumann AG	
Indications for Use	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.		**Identical**
Implant to abutment interface	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)		**Identical**
Gingival Height	1.5 and 2.5 mm	1.5 and 2.5 mm		**Identical**
Reusable	No	No		**Identical**
Material	Zirconia Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy, according to ASTM F136 standard.	Zirconia Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy, according to ASTM F136 standard.		**Identical**
Design workflow	Digital Workflow: Zirconia Base library on Dental Wings and 3Shape. Conventional Workflow: manually designed by the technician	Digital Workflow: Zirconia Base library on Dental Wings and 3Shape.	Digital Workflow: CARES® Visual. Conventional Workflow: manually designed by the technician	**Equivalent** The digital workflow remains the same and the conventional workflow is done manually as the reference predicate device.
Manufacturing workflow	Digital Workflow: Straumann Milling Center Conventional Workflow: in-lab (traditional pressing)	Digital Workflow: Straumann Milling Center	Digital Workflow: Straumann Milling Center Conventional Workflow: in-lab (traditional casting or pressing)	**Equivalent** The digital workflow remains the same and the conventional workflow (subject of this submission) is the same of the reference predicate device (traditional pressing).

<table>
<tr><th></th><th>SUBJECT DEVICE
Neodent Implant System – Zirconia Implant System
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>PRIMARY PREDICATE DEVICE
K201491
Neodent Implant System
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>REFERENCE DEVICE
K142890
Straumann® Variobase™ Abutments
Institut Straumann AG</th><th>EQUIVALENCE DISCUSSION</th></tr>
<tr><td>Restoration Material</td><td>Digital Workflow:<table><tr><th>Material</th><th>Minimum wall thickness</th><th>Minimum angulation</th><th>Maximum angulation</th></tr><tr><td>3M ESPE Lava Plus Zirconia</td><td>0.7 mm</td><td rowspan="3">0°</td><td rowspan="3">30°</td></tr><tr><td>Zirconia (Zerion LT)</td><td>0.4 mm</td></tr><tr><td>Zirconia (Zerion UTML)</td><td>0.5 mm</td></tr></table>Conventional Workflow:<table><tr><th>Material</th><th>Minimum wall thickness</th><th>Minimum angulation</th><th>Maximum angulation</th></tr><tr><td>IPS e.max Press</td><td>0.9 mm</td><td>0°</td><td>30°</td></tr></table></td><td>Digital Workflow:<table><tr><th>Material</th><th>Minimum wall thickness</th><th>Minimum angulation</th><th>Maximum angulation</th></tr><tr><td>3M ESPE Lava Plus Zirconia</td><td>0.7 mm</td><td rowspan="3">0°</td><td rowspan="3">30°</td></tr><tr><td>Zirconia (Zerion LT)</td><td>0.4 mm</td></tr><tr><td>Zirconia (Zerion UTML)</td><td>0.5 mm</td></tr></table></td><td>Digital Workflow:<table><tr><th>Material</th><th>Minimum wall thickness</th><th>Minimum angulation</th><th>Maximum angulation</th></tr><tr><td>Zerion</td><td>0.4 mm</td><td rowspan="4">0°</td><td rowspan="4">30°</td></tr><tr><td>IPS e.max CAD</td><td>0.9 mm</td></tr><tr><td>Coron</td><td>0.3 mm</td></tr><tr><td>Polycon ae</td><td>0.5 mm</td></tr></table>Conventional Workflow:<table><tr><th>Material</th><th>Minimum wall thickness</th><th>Minimum angulation</th><th>Maximum angulation</th></tr><tr><td>IPS e.max Press (in-lab pressing)</td><td>0.9 mm</td><td>0°</td><td>30°</td></tr><tr><td>Type 4 dental metals (ISO 22674) (In-lab casting).</td><td>0.5 mm</td><td>0°</td><td>30°</td></tr></table></td><td>Equivalent
The digital workflow remains the same when compared to primary predicate device. The change of this submission is related to conventional workflow and inclusion of IPS e.max Press indication to Zirconia Bases. However, when compared to reference predicate device, the restorative material (IPS e.max Press) is equivalent.</td></tr>
<tr><td>Sterilization Method</td><td>Provided sterile via Ethylene Oxide to an SAL of 10^{-6}. End user sterilized via moist heat following cementation of coping and before use.</td><td>Provided sterile via Ethylene Oxide to an SAL of 10^{-6}. End user sterilized via moist heat following cementation of coping and before use.</td><td></td><td>Identical</td></tr>
</table>

PERFORMANCE DATA

Mechanical testing

In order to demonstrate the substantial equivalence regarding the mechanical strength of the system, the dynamic fatigue test was performed using the new restoration material, in accordance with ISO 14801 and FDA guidance document "*Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*". The performance bench test carried out with the Zirconia Bases and IPS e.max Press demonstrates that the new material is substantially equivalent to the previously cleared materials.

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 do not configure a new worst case and can be represented by the previously conducted studies reviewed for primary predicate devices, since both have the same raw material and similar dimensions. The subject devices are therefore MR conditional devices and a patient treated with the subject devices can be safely scanned observing the parameters previously established per primary predicate devices.

Sterilization validation

Sterilization of the Zirconia Abutments via ethylene oxide gas using the overkill method has been performed according to the requirements of ISO 11135-1 Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements For Development, Validation and Routine Control of a Sterilization Process For Medical Devices. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.

Steam sterilization have been performed according to ISO 17665-1 Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. The worst case device in conjunction with lithum dissilicate restoration material (IPS) was already validated for steam sterilization, using the parameters described in IFU, under reference device evaluation (K163194).

Biocompatibility

A biological assessment was performed according to ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process 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. No new issues of biocompatibility are raised for the Zirconia Bases when compared to primary predicate and restoration and cement materials when compared to reference devices (K223638). Therefore, no additional biocompatibility testing was required.

CONCLUSION

The results of the comparison between the subject and predicates devices demonstrate that they are substantially equivalent.