July 06, 2021

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

Re: K203309
Trade/Device Name: NUVO CF Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 5, 2021
Received: June 7, 2021

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 Andrew Steen
Assistant 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)*
K203309

Device Name
NUVO CF Implant System

Indications for Use *(Describe)*
Indications for Use for NUVO CF Implants:

The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for NUVO CF Traditional Abutments:

The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for Attachment Equator CF:

The Attachment Equator CF is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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.
The Attachment Equator abutments are indicated for the attachment of full or partial dentures to NUVO implants.

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)*
K203309

Device Name
NUVO CF Implant System

Indications for Use *(Describe)*
Indications for Use for Attachment Removable Prosthesis CF:

The Attachment Removable Prosthesis CF is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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. The Attachment Removable Prosthesis abutments are indicated for the attachment of full or partial dentures to Nuvo implants.

Indications for Use for Temporary Abutments CF for Crown and for Bridge:

The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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 Titanium Temporary Abutment is indicated to provide temporary support for prosthesis structure for up to 6 months.

Indications for Use for CF Titanium Base for Crown:
CF Titanium Base for Crown is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations, as copings or crowns. It is indicated for single-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium 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)

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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)*
K203309

Device Name
NUVO CF Implant System

Indications for Use *(Describe)*
Indications for Use for CF Titanium Base for Bridge:

CF Titanium Base for Bridge is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations. The CF Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Cares Abutment CF:

The CARES® Abutment CF is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations (copings or crowns). It is indicated for screw-retained or cement-retained single restorations. All digitally designed abutments for use with the CARES® Abutment are intended to be sent to Straumann for manufacturing 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)

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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	06/07/2021
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DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	NUVO CF Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Name	Implant, Endosseous, Root-form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II 21 CFR 872.3630, Class II
Product Code	Primary: DZE Secondary: NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K193234 – NUVO IF Implant System, JJGC Indústria e Comércio de Materiais Dentários SA
Reference Predicate Device	K173961 - Straumann® BLX Implant System, Institut Straumann AG K182620 - MRI Compatibility for Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Indications for Use for NUVO CF Implants:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for NUVO CF Traditional Abutments:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for Attachment Equator CF:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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.
The Attachment Equator abutments are indicated for the attachment of full or partial dentures to NUVO implants.

Indications for Use for Attachment Removable Prosthesis CF:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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.
The Attachment Removable Prosthesis abutments are indicated for the attachment of full or partial dentures to Nuvo implants.

Indications for Use for Temporary Abutments CF for Crown and for Bridge:
The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used with singlestage 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 Titanium Temporary Abutment is indicated to provide temporary support for prosthesis structure for up to 6 months.

Indications for Use for CF Titanium Base for Crown:
CF Titanium Base for Crown is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations, as copings or crowns. It is indicated for single-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for CF Titanium Base for Bridge:
CF Titanium Base for Bridge is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations. The CF Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Cares Abutment CF:
The CARES® Abutment CF is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations (copings or crowns). It is indicated for screw-retained or cement-retained single-unit restorations.
All digitally designed abutments for use with the CARES® Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.

SUBJECT DEVICE DESCRIPTIONS

Implants

- Intended for single use;
- Provided sterile via gamma irradiation
- Manufactured of commercially pure titanium (Grade 4) per ASTM F67;
- Bone level design
- Apically tapered thread-form with apical cutting flutes in 3.5 and 3.75 mm diameters with lengths of 8, 10, 11.5, 13, 16 & 18 mm, 4.0 and 4.3 mm diameters with lengths of 7, 8, 10, 11.5, 13, 16 & 18 mm and in 5.0 mm diameter with lengths of 7, 8, 10, 11.5, 13 & 16 mm.
- Provided with an internal hexagonal implant-to-abutment interface compatible with the subject Cover Screw and Abutments.

Cover Screws

- Intended for single use;
- Used to protect the internal geometry of the subject Nuvo CF implants during the healing phase when a two-stage protocol is used;
- Placed out of occlusion;
- Provided sterile via gamma irradiation in the same barrier package as the subject implants—also provided individually packaged in sterile condition via ethylene oxide gas;
- Manufactured of titanium alloy (Ti6Al4V-ELI) per ASTM F136;
- Provided with an implant-to-abutment interface compatible with the internal hexagonal geometry of the subject Nuvo CF implants.

Abutments

- Intended for single use;
- All the abutments are provided sterile via ethylene oxide gas, with exemption of the Cobalt-Chromium UCLA CF and the CARES Abutment CF, which are delivered non-sterile. Both products must be sterilized before use, as indicated in their IFU.
- Manufactured of titanium alloy (Ti6Al4V-ELI) per ASTM F136 or in a combination of POM (Polyoxymethylene) polymer and cobalt-chromium alloy (CoCr), conforming to ASTM F1537;
- Conical format available in different diameters, height of cementable area and gingival height;
- Screw-retained to the implant;
- Provided with an implant-to-abutment interface compatible with the internal hexagonal geometry of the subject Nuvo CF implants;
- Provided with coronal geometries in rotational (non-indexed) versions to support multi-unit restorations and in anti-rotational (indexed) versions to support single restorations

SUBSTANTIAL EQUIVALENCE COMPARISON TABLES

The Substantial Equivalence Comparison tables are provided on the pages that follow below.

Table 1: Substantial Equivalence Comparison – Indication for Use Statements

COMPARISON	SUBJECT DEVICES **K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use Statement	Indications for Use for NUVO CF Implants The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for NUVO CF Traditional Abutments: The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 for Attachment Equator CF: The Attachment Equator is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. The Attachment Equator abutments are indicated for the attachment of full or partial dentures to NUVO implants. Indications for Use for Attachment Removible Prosthesis CF: The Attachment Removable Prosthesis is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. The Attachment Removable Prosthesis abutments are indicated for the attachment of full or partial dentures to NUVO implants. Indications for Use for Temporary Abutment CF for Crown and for Bridge: The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 Titanium Temporary Abutment is indicated to provide temporary support for prosthesis structure for up to 6 months. Indications for Use for Titanium Bases for Crown: Titanium Base for Crown is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations, as copings or crowns. It is indicated for single-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	Indications for Use for NUVO IF Implants and conventional abutments: The NUVO IF Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 Titanium Temporary Abutment is indicated to provide temporary support for prosthesis structure for up to 6 months. The Attachment Equator and Attachment Removable Prosthesis abutments are indicated for the attachment of full or partial dentures to NUVO implants. Indications for Use for Rotational and Anti-rotational Titanium Bases abutments: Titanium Base Abutment is a titanium base placed onto 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 to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. The Rotational Titanium Base is indicated for cement or screw-retained multi-unit restorations. Indications for Use for CARES® Abutment IF: The CARES® Abutment is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations (copings or crowns). It is indicated for screw-retained or cement-retained single restorations. All digitally designed abutments for use with the CARES® Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE
	K203309 NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.
	Indications for Use for Titanium Base for Bridge: CF Titanium Base for Bridge is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations. It is indicated for cement or screw-retained multi-unit restorations. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for Cares Abutment CF: The CARES® Abutment CF is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations (copings or crowns). It is indicated for screw-retained or cement-retained single-unit restorations. All digitally designed abutments for use with the CARES® Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.	

The scope of the Indications for Use Statement for the subject devices (Implants and Conventional Abutments) are equivalent to the corresponding section of the Indications for Use Statement of the primary predicate device K193234, only with greater separation between product categories. The main language difference is in the indication for use of the Attachment Equator and Attachment Removable Prosthesis, since the indication presented to these devices are specific to the products, and therefore recommended for multiple restorations only. The indication for use presented to the predicate devices is applicable for all the implant system, and therefore recommended for both types of restorations. However, the subject devices are covered by the predicate devices since the predicate indication for use is more comprehensive.

The Indications for Use Statement for the subject device (Titanium Base for Crown and Titanium Base for Bridge abutments) are equivalent to the corresponding section of the Indications for Use Statement of K193234, except for the names of the devices and the greater separation between product categories. The language difference between the indications for use occurs again due to the indication applied to the reference devices being more comprehensive, for both types of bases. While for the subject devices the indication is presented separately and specific for each type of base in the Indications for Use Statement form.

The indication for use for the subject device (CF CARES® ABUTMENT) was not initially included in the Indications for Use Statement and is being added in this review.

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

Table 2: Substantial Equivalence Comparison – Implants

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant Type	Bone Level	Bone Level	**Identical** The subject devices have the same external design as the primary predicate.
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Implant Diameter	3.5 mm, 3.75 mm, 4.0, 4.3 mm and 5.0 mm	3.5 mm, 3.75 mm, 4.3 mm and 5.0 mm	**Equivalent** The subject device diameters are in the range of diameters of the primary predicate devices.
Implant Length	3.5 mm: 8, 10, 11.5, 13, 16 & 18 mm 3.75 mm: 8, 10, 11.5, 13, 16 & 18 mm 4.0 mm: 7, 8, 10, 11.5, 13, 16 & 18 mm 4.3 mm: 7, 8, 10, 11.5, 13, 16 & 18 mm 5.0 mm: 7, 8, 10, 11.5, 13 & 16 mm	3.5 mm: 7, 10, 11.5, 13, 16 & 18 mm 3.75 mm: 7, 10, 11.5, 13, 16 & 18 mm 4.3 mm: 7, 10, 11.5, 13, 16 & 18 mm 5.0 mm: 7, 10, 11.5, 13 & 16 mm	**Equivalent** The subject device lengths are within the range established by the primary predicate devices.
Thread Design	Apically Tapered, Dual Helix	Apically Tapered, Dual Helix	**Identical** The subject devices have the same thread design as the primary predicate.
Surface Finish	Sand blasted and acid etched	Sand blasted and acid etched	**Identical** Subject and primary predicate devices have the same surface finish (Neoporos).
Material	Commercially Pure Titanium (Grade 4)	Commercially Pure Titanium (Grade 4)	**Identical** Subject and primary predicate devices have the same material of construction.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Sterilization Method	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	**Identical** Subject and primary predicate devices utilize the same sterilization method and minimum SAL.

Table 3: Substantial Equivalence Comparison – Cover Screw

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Screw used to protect internal features of the implant during submerged healing protocol. **Apical Geometry** = Internal Hex **Material** = Titanium Alloy (Ti-6Al-4V)	Screw used to protect internal features of the implant during submerged healing protocol. **Apical Geometry** = Internal Hex **Material** = Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar apical geometry.
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined and Electrolysis (only NP platform)	Machined and Electrolysis (only NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 4: Substantial Equivalence Comparison – Healing Abutment

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Screw having a coronal geometry to define gingiva shape during delayed loading protocols. **Angulation**: 0° **Coronal Geometry**: Smooth emergence profile in multiple heights to address different gingiva types **Apical Geometry**: Internal Hex **Material** = Titanium Alloy (Ti-6Al-4V)	Screw having a coronal geometry to define gingiva shape during delayed loading protocols. **Angulation**: 0° **Coronal Geometry**: Smooth emergence profile in multiple heights to address different gingiva types **Apical Geometry**: Internal Hex **Material** = Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometry.
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined and Electrolysis (only NP platform)	Machined and Electrolysis (only NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 5: Substantial Equivalence Comparison – Cement Retained Abutment CF

COMPARISON	SUBJECT DEVICES **Subject** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0°, 17° & 25° **Coronal Geometry**: Generally conical shape **Gingival Height:** NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0°, 17° & 25° **Coronal Geometry**: Generally conical shape **Gingival Height:** NP – 0.5, 1, 2 & 3 mm SP – 0.5, 1, 2 & 3 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometry. Worst-case angulation equivalent to primary predicate devices.
Surface treatment	NP platform: Electrolysis SP Platform: Machined	NP platform: Electrolysis SP Platform: Machined	**Identical** Both subject and predicate devices present the same surface treatment
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined and Electrolysis (only NP platform)	Machined and Electrolysis (only NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 6: Substantial Equivalence Comparison – Multi-Unit Screw Retained Abutment CF

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment designed to accept a screw-retained prosthetic. **Angulation**: 0°, 17° & 30° **Coronal Geometry**: Generally conical shape **Gingival Height:** NP – 1, 2, 2.5, 3, 3.5, 4 & 5 mm SP – 1, 2, 2.5, 3, 3.5, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** indexed (angled abutments) and non-indexed (straight abutments) **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a screw-retained prosthetic. **Angulation**: 0°, 17° & 30° **Coronal Geometry**: Generally conical shape **Gingival Height:** NP – 0.5, 1, 2, 2.3, 3, 4 & 5 mm SP – 1, 2, 2.3, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** indexed (angled abutments) and non-indexed (straight abutments) **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometry.
Surface treatment	NP platform: Electrolysis SP Platform: Machined	NP platform: Electrolysis SP Platform: Machined	**Identical** Both subject and predicate devices present the same surface treatment
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined and Electrolysis (only NP platform)	Machined and Electrolysis (only NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 7: Substantial Equivalence Comparison – Attachment Equator CF

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment to accept detachable over-denture prostheses. **Angulation**: 0° **Coronal Geometry**: To accept o-ring style matrices **Gingival Height:** NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment to accept detachable over-denture prostheses. **Angulation**: 0° **Coronal Geometry**: To accept o-ring style matrices **Gingival Height:** NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometry.
Surface treatment	NP platform: Electrolysis SP Platform: Machined	NP platform: Electrolysis SP Platform: Machined	**Identical** Both subject and predicate devices present the same surface treatment
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined with titanium nitride (TiN) coating	Machined with titanium nitride (TiN) coating	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 8: Substantial Equivalence Comparison – Attachment Removable Prosthesis CF

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment to accept detachable over-denture prostheses. **Angulation**: 0° **Coronal Geometry**: To accept Valoc Novaloc matrices **Gingival Height:** NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment to accept detachable over-denture prostheses. **Angulation**: 0° **Coronal Geometry**: To accept Valoc Novaloc matrices **Gingival Height:** NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometry.
Surface treatment	NP platform: Electrolysis SP Platform: Machined	NP platform: Electrolysis SP Platform: Machined	**Identical** Both subject and predicate devices present the same surface treatment
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined with titanium nitride (TiN) coating	Machined with titanium nitride (TiN) coating	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 9: Substantial Equivalence Comparison – Cobalt-Chromium UCLA CF

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment to facilitate the casting of base metal and precious metal alloy prostheses. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical **Gingival Height:** 1 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** CoCr Alloy with POM polymer	Abutment to facilitate the casting of base metal and precious metal alloy prostheses. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical **Gingival Height:** 1 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** CoCr Alloy with POM polymer	**Equivalent** The subject devices share the same coronal and apical geometry as the primary predicate device.
Sterilization Method	Provided non-sterile. Terminally sterilized by the user via moist heat. Moist heat cycle parameters have been validated to an SAL of 1×10^{-6}.	Provided non-sterile. Terminally sterilized by the user via moist heat. Moist heat cycle parameters have been validated to an SAL of 1×10^{-6}.	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined and Electrolysis (only NP platform)	Machined and Electrolysis (only NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 10: Substantial Equivalence Comparison – Titanium Temporary Abutments CF for Crown and for Bridge

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment for the creation of a temporary, non-occlusal restoration to address esthetics during fabrication of final prosthesis. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical with grooves to bond acrylic resins **Gingival Height:** 1 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment for the creation of a temporary, non-occlusal restoration to address esthetics during fabrication of final prosthesis. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical with grooves to bond acrylic resins **Gingival Height:** 1 mm **Apical Geometry**: Internal Hex **Indexing:** Both indexed and non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share similar coronal and apical geometries.
Sterilization Method	• Ethylene Oxide to an SAL of $1x10^{-6}$ • If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.	• Ethylene Oxide to an SAL of 1x10-6 • If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface Treatment	Machined (SP platform) Machined and Electrolysis (NP platform)	Machined (SP platform) Machined and Electrolysis (NP platform)	**Identical** Subject and primary predicate devices utilize the same surface treatment.

Table 11: Substantial Equivalence Comparison – CF Titanium Base for Crown (Antirotational)

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173961** Straumann® BLX Implant System Institut Straumann AG	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical shape **Platform ∅:** NP – 3.5 & 4.5 mm SP – 4.5 & 5.5 mm **Gingival Height:** NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical shape **Platform ∅:** NP – 3.5 mm SP – 4.5 & 5.5 mm **Gingival Height:** NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical shape **Platform ∅:** 3.8, 4.5, 5.5 mm **Gingival Height:** 0.75 – 2.5 mm **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Niobium Alloy (Ti-6Al-7Nb)	**Equivalent** The subject devices and the primary predicate devices (K193234) share similar coronal and apical geometry. The subject devices present dimensions contained within the range of dimension of the predicate devices (K173961).
CAD/CAM Restoration Angulation	Up to 30°	Up to 30°	Up to 30°	**Identical** Subject and predicate devices present the same CAD/CAM Restoration Angulation.

<table>
<tr><th>COMPARISON</th><th>SUBJECT DEVICES
Subject
NUVO CF Implant System
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>PRIMARY PREDICATE
K193234
NUVO IF Implant System
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>REFERENCE PREDICATE
K173961
Straumann® BLX Implant System
Institut Straumann AG</th><th>EQUIVALENCE DISCUSSION</th></tr>
<tr><td>Top half materials</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness (mm)</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="4">30°</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
<tr><td>Zerion LT</td><td>0.5</td></tr>
<tr><td>Polycon ae*</td><td>1.0</td></tr>
</table>
The CF Titanium Base for Crown with 6 mm cementable height are supplied without angulation, but allow customization by reducing the height of cementable area to 4 mm.
*Polycon ae is indicated to remain in the mouth only for up to 180 days</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness (mm)</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="3">30°</td></tr>
<tr><td>Zirconia (Zerion LT)</td><td>0.5</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
</table>
The IF Titanium Base for Crown with 6 mm cementable height allows its customization to 4 mm. In the case of angled structures, the maximum overall height of the restoration cemented to the Titanium Base cannot exceed 10 mm.</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness (mm)</th><th>Maximum allowable angulation</th></tr>
<tr><td>Polycon ae*</td><td>0.5</td><td rowspan="2">30°</td></tr>
<tr><td>IPS e.max CAD</td><td>0.7</td></tr>
</table>
*Polycon ae is indicated to remain in the mouth only for up to 180 days</td><td>Equivalent
The subject top half materials are contained within the scope of the cleared top half materials for the predicate devices and using the same cleared design parameters.
The subject Titanium Base for Crown, when combined with Polycon ae restoration, can remain in the mouth for the same time indicated in the reference predicate devices K173961.</td></tr>
<tr><td>Surface treatment</td><td>NP platform: Electrolysis
SP Platform: Machined</td><td>NP platform: Electrolysis
SP Platform: Machined</td><td>Machined</td><td>Identical
Both subject and predicate devices (K193234) present the same surface treatment.</td></tr>
<tr><td>Sterilization Method</td><td>• Ethylene Oxide to an SAL of $1x10^{-6}$
• If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.</td><td>• Ethylene Oxide to an SAL of 1x10-6
• If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.</td><td>Non-sterile/End user sterilized</td><td>Identical
The subject devices and the predicate devices (K193234) share the same sterilization method.</td></tr>
</table>

Table 12: Substantial Equivalence Comparison – CF Titanium Base for Bridge (Rotational)

COMPARISON	SUBJECT DEVICES **Subject** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K173961** Straumann® BLX Implant System Institut Straumann AG	EQUIVALENCE DISCUSSION
Implant-to-Abutment Interface	Internal Hex	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Conical shape with grooves **Platform ∅:** NP – 3.5 & 4.5 mm SP – 4.5 & 5.5 mm **Gingival Height:** NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Conical shape with grooves **Platform ∅:** NP – 3.5 mm SP – 4.5 & 5.5 mm **Gingival Height:** NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm **Apical Geometry**: Internal Hex **Indexing:** Non-indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Abutment designed to accept a cement-retained prosthetic. **Angulation**: 0° **Coronal Geometry**: Generally cylindrical shape **Platform ∅:** 3.8, 4.5, 5.5 mm **Gingival Height:** 0.75 – 2.5 mm **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Niobium Alloy (Ti-6Al-7Nb)	**Equivalent** The subject devices and the primary predicate devices (K193234) share similar coronal and apical geometry. The subject devices present dimensions contained within the range of dimension of the predicate devices (K173961).
CAD/CAM Restoration Angulation	Up to 30°	Up to 30°	Up to 30°	**Identical** Subject and predicate devices present the same CAD/CAM Restoration Angulation.
Top half materials	**Material** / **Minimum thickness (mm)** / **Maximum allowable angulation** Coron (CoCr) 0.3 30° Zerion LT 0.5 Polycon ae* 1.0 The restorative element to be bonded to the Titanium Base shall have a minimum height of 4.9 mm and a maximum height of 10 mm from the restorative base at the coronal end of the gingival collar. The post height of 4.5 mm cannot be reduced. *Polycon ae is indicated to remain in the mouth only for up to 180 days	**Material** / **Minimum thickness (mm)** / **Maximum allowable angulation** Coron (CoCr) 0.3 30° Ticon (Titanium) 0.4 Zirconia (Zerion LT) 0.5 The -IF Titanium Base for Bridge with 6 mm cementable height allows its customization to 4 mm. In the case of angled structures, the maximum overall height of the restoration cemented to the Titanium Base cannot exceed 10 mm.	**Material** / **Minimum thickness (mm)** / **Maximum allowable angulation** Polycon ae* 0.5 30° IPS e.max CAD 0.7 *Polycon ae is indicated to remain in the mouth only for up to 180 days	**Equivalent** The subject top half materials are contained within the scope of the cleared top half materials for the predicate devices and using the same cleared design parameters. The subject Titanium Base for Bridge, when combined with Polycon ae restoration, can remain in the mouth for the same time indicated in the reference predicate devices K173961.

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATE	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173961** Straumann® BLX Implant System Institut Straumann AG	
Surface treatment	NP platform: Electrolysis SP Platform: Machined	NP platform: Electrolysis SP Platform: Machined	Machined	**Identical** Both subject and predicate devices (K193234) present the same surface treatment.
Sterilization Method	• Ethylene Oxide to an SAL of 1x10-6 • If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 135°C (270°F) for 3 minute exposure.2	• Ethylene Oxide to an SAL of 1x10-6 • If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.	Non-sterile/End user sterilized	**Identical** The subject devices and the predicate devices (K193234) share the same sterilization method.

Table 13: Substantial Equivalence Comparison – Titanium Blank CF

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Abutment Design	Milling blank with the Implant-to-Abutment interface pre-milled at one end. Used to fabricate patient-specific abutments. **Angulation**: 0° **Coronal Geometry**: Oversize cylinder for milling 11.5 mm & 15.8 mm diameters **Gingival Height:** Not Applicable **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Alloy (Ti-6Al-4V)	Milling blank with the Implant-to-Abutment interface pre-milled at one end. Used to fabricate patient-specific abutments. **Angulation**: 0° **Coronal Geometry**: Oversize cylinder for milling 11.5 mm & 15.8 mm diameters **Gingival Height:** Not Applicable **Apical Geometry**: Internal Hex **Indexing:** Indexed **Material:** Titanium Alloy (Ti-6Al-4V)	**Equivalent** The subject devices and the primary predicate devices share the same coronal and apical geometry.
Sterilization Method	Provided Non-Sterile Terminally sterilized by user via moist steam via parameters validated to an SAL of $1x10^{-6}$	Provided Non-Sterile Terminally sterilized by user via moist steam via parameters validated to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.
Surface treatment	Machined (SP platform) Machined and Electrolysis (NP platform)	Machined (SP platform) Machined and Electrolysis (NP platform)	**Identical** Both subject and predicate devices present the same surface treatment.

Table 14: Substantial Equivalence Comparison – Cares Abutment CF

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Operating principles	Milling blank with the Implant-to-Abutment interface premilled at one end. Used to fabricate patient-specific abutments that are indicated with screw-retained or cement-retained single restorations	Milling blank with the Implant-to-Abutment interface premilled at one end. Used to fabricate patient-specific abutments that are indicated with screw-retained or cement-retained single restorations	**Equivalent** The operating principles of subject device is the same as the reference predicate device.
Implant-to-Abutment Interface	Internal Hex	Internal Hex	**Equivalent** The implant interface is equivalent to that of the primary predicate device.
Single Use	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Diameter	Oversize cylinder for milling 11.5 mm & 15.8 mm diameters Platform Ø: NP – 3.1 SP – 3.6	Oversize cylinder for milling 11.5 mm & 15.8 mm diameters Platform Ø NP – 3.5 SP – 4.5	**Identical** Subject and predicate devices present the same dimensions.
Gingival Height	NP – minimum 0.8 mm SP – minimum 0.8 mm	NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm	**Equivalent** The minimum gingival height of the subject devices is within the range of the gingival heights of the predicate device
Angulation	Straight Angulation of milled abutment: up to 30°	Straight Angulation of milled abutment: up to 30°	**Equivalent** The abutments of the subject devices and the primary predicate devices are provided straight and allow a maximum angulation of up to 30° for the milled abutment.
Raw material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Identical** Subject and predicate devices are manufactured of the same raw material
Surface Treatment	Machined (SP platform) Machined and anodized (NP platform)	Machined (SP platform) Machined and anodized (NP platform)	**Identical** Subject and predicate devices present the same surface treatment
Sterilization Method	Provided Non-Sterile Terminally sterilized by user via moist steam via parameters validated to an SAL of $1x10^{-6}$	Provided Non-Sterile Terminally sterilized by user via moist steam via parameters validated to an SAL of $1x10^{-6}$	**Identical** The subject devices and the primary predicate devices share the same sterilization method.

NON-CLINICAL PERFORMANCE DATA

Biocompatibility

Biological Safety Assessment for the subject devices was guided by ISO 10993-1 and FDA guidance. Biocompatibility for the subject devices was leveraged from the primary predicate K193234 and reference predicate K173961.

Package transport integrity testing has been performed per ISTA 2A.

Product and package stability have been validated per ASTM F1980.

The implant and abutment surfaces are the same as the cleared predicate devices.

Bench testing

Dynamic fatigue test per ISO 14801 and FDA guidance was performed to determine the fatigue strength for the worst-case constructs assembled using the subject devices.

MRI compatibility testing was leveraged from the reference device K182620.

Sterilization validation

Sterilization of the subject endosseous dental implant devices via gamma irradiation was validated per ISO 11137-1 and ISO 11137-2. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.

Sterilization of the subject abutments via ethylene oxide gas was validated per ISO 11135. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.

The Subject devices are not represented to be "pyrogen free".

Ethylene oxide residuals have been assessed per ISO 10993-7. Residuals are within accepted limits.

Bacterial Endotoxin Testing are performed on representative samples selected and tested based upon the raw material, manufacturing processes and sterilization process, according to ANSI/AAMI ST72:2011, Bacterial Endotoxins – Test Methods, Routine Monitoring and Alternatives to Batch Testing. The obtained results were <0,05 EU/device.

CONCLUSION

The subject devices and the predicate devices have equivalent intended use, design and technological characteristics. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices