June 18, 2020

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

Re: K193234
Trade/Device Name: NUVO IF Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 19, 2020
Received: May 20, 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)*
K193234

Device Name
NUVO IF Implant System

Indications for Use *(Describe)*

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 or screw-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.

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

K193234

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	17 June 2020
Preparer / Alternate Contact	Luiza Vaccari Toppel Regulatory Affairs Coordinator JJGC Indústria e Comércio de Materiais Dentários SA E-mail: luiza.toppel@neodent.coml

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	NUVO IF Implant System
Common Name	Endosseous dental implant
Classification Name(s)	Endosseous dental implant
Classification Regulation(s)	21 CFR 872.3640, Class II
Product Code(s)	DZE; NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K101945 – Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA
Reference Predicate Devices	K150203 – Medentika CAD/CAM Abuments, Medentika GmbH K150367 – Neodent Implant System, JJGC K153624 - Neodent Implant System, JJGC K163194 – Neodent Implant System - GM Line, JJGC K173902 – Neodent Implant System - GM Line, JJGC K190040 - Straumann BLX Line Extension - New Abutments, Institut Straumann AG K190718 – GM Zygomatic Implants, JJGC K191191 - Neodent Implant System – Temporary Abutments, JJGC K192229 – Neodent Implant System – Neodent Titanium Base for Bridge, JJGC

INDICATIONS FOR USE

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.

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, 3.75 & 4.3 mm diameters with lengths of 7, 10, 11.5, 13, 16 & 18 mm and in 5.0 mm diameter with lengths of 7, 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 IF 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 IF implants.

Abutments

- Intended for single use;
- Provided sterile via ethylene oxide gas or non-sterile
- 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 IF 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
- Titanium Base abutments are two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLES

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

Table 1: Substantial Equivalence – Indication for Use Statements

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATES				
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150367** Neodent Implant System – TiBase & Preface JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192229** Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System – Temporary Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190040** Straumann® PUREloc abutments Institut Straumann AG
Indications for Use Statement	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	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.	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. PreFace Abutment 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. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.	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	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 to be used with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. The GM Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations.	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 - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann implants

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATES				
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150367** Neodent Implant System – TiBase & Preface JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192229** Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System – Temporary Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190040** Straumann® PUREloc abutments Institut Straumann AG
	validated milling center. The Rotational Titanium Base is indicated for cement or screw-retained multi-unit restorations. <u>Indications for Use for CARES® Abutment IF:</u> 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.			intended to be sent to Straumann for manufacture at a validated milling center. <u>Indications for Use for GM Pro Peek Abutments:</u> 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.			

The scope of the Indications for Use Statement for the subject devices (implants and conventional abutments section) are contained within the corresponding section of the Indications for Use Statement of the primary predicate device K101945. The specific languages for Titanium Temporary Abutment and Attachment Equator/Attachment Removable Prosthesis are the same of the corresponding section of the Indications for Use Statement of K191191 (Neodent Implant System – Temporary Abutments) and K190040 (Straumann® PUREloc abutments), except for the names of the devices.

The Indications for Use Statement for the subject device (Rotational and Anti-rotational Titanium Bases abutments section) is identical to the corresponding section of the Indications for Use Statement of K163194 (GM Titanium Base abutments section), except for the names of the devices. The specific indication for use for Titanium Base Rotational is the same of K192229 (Neodent Implant System – GM Titanium Base for Bridge).

The Indications for Use Statement for the subject device (CARES® Abutment IF section) is similar to the PreFace section of the Indications for Use Statement of the reference device K150367. The slight differences are the names of the devices and, for the subject device statement, the requirement to manufacture at a Straumann milling center. For K150367 the requirement to manufacture at a Straumann milling center was included in the labeling. The slight differences in wording between the Indications for Use Statements for the subject device and the reference device K150367 do not affect the intended use with dental implants for rehabilitation of the edentulous maxilla or mandible.

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 – Technological characteristics - Implants

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K101945** Neodent Implant System – CM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Implant Type	Bone Level	Bone Level		**Same** The subject devices have the same external design as the primary predicate.
Implant-to-Abutment Interface	Internal Hex	Cone Morse		**Equivalent** The implant interface is equivalent to that of the predicate. Dynamic fatigue testing has been performed to establish the performance of the interface.
Implant Diameter	3.5 mm, 3.75 mm, 4.3 mm and 5.0 mm	3.5 mm, 4.3 mm and 5.0 mm	3.5 to 5.0 mm	**Equivalent** The subject device diameters are in the range of diameters of the primary and reference predicate devices.
Implant Length	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	<u>Alvim CM Implant</u> All diameters: 8, 10, 11.5, 13 & 16 mm <u>Titamax CM Implant</u> 3.5 mm: 7, 8, 9, 11, 12, 15 & 17mm 3.75 mm: 7, 8, 9, 11, 12, 15 & 17mm 4.0 mm: 7, 8, 9, 11, 12, 15 & 17mm 5.0 mm: 7, 8, 9, 11, 12, 15 & 17mm	8 to 18 mm	**Equivalent** The subject device lengths are within the range established by the primary and reference predicate devices.
Thread Design	Apically Tapered, Dual Helix	Apically Tapered, Dual Helix (Trade Name = Alvim)		**Same**
Surface Finish	Sand blasted and acid etched	Sand blasted and acid etched (Trade Name = Neoporos)		**Same**
Material	Commercially Pure Titanium (Grade 4)	Commercially Pure Titanium (Grade 4)		**Same**
Single Use	Yes	Yes		**Same**
Sterilization Method	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$		**Same**

Table 3: Substantial Equivalence Comparison – Technological characteristics – Traditional Abutments (Cover Screw/Healing Abutment/Multi-Unit Abutment/Cement Retained Abutment)

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Cover Screw/Healing Abutment			
Principal of operation	Screw used to protect internal features of the implant during submerged healing protocol and to define gingiva shape during delayed loading protocols.	Conditioning the soft tissues and closing the implant interface during healing phase.	**Equivalent** The principal of operation of subject device is equivalent of the primary and reference predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Diameter	Cover Screw Platform ∅: NP – 3.5 mm | SP – 4.5 mm Healing Abutment Platform ∅: NP – 3.5 mm | SP – 4.5 mm and 5.5 mm	Conventional abutments: 3.5 to 4.5 mm	**Equivalent** Subject device diameters are within the range of diameters of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
Gingival Height	1.0, 3.0 and 5.0 mm	0.8 to 6.5 mm	**Equivalent** Subject device heights are included in the range of the predicate device heights.
Angulation	Straight	Straight	**Same**
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined and anodized (only NP platform)	Machined and anodized	**Same**
Single Use	Yes	Yes	**Same**
Sterilization Method	Co-packaged implant and cover screw Gamma Irradiation to an SAL of $1x10^{-6}$ Cover screw and Healing provided individually Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Equivalent** The subject device when provided co-packaged with the implant share the same sterilization method and minimum SAL of the reference predicate device. The subject devices when provided individually share the same sterilization method and minimum SAL of the primary predicate device.
Multi-Unit Abutment			
Principal of operation	Abutment designed to accept a screw-retained prosthetic.	To support final restorations when placed on implants.	**Equivalent** The principal of operation of subject device is equivalent of the primary and reference predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Indexing	Indexed (angled abutments) and non-indexed (straight abutments)	Indexed (angled abutments) and non-indexed (straight abutments)	**Same**
Diameter	Platform ∅: NP – 3.5 & 4.8 mm SP – 4.8 mm	Platform ∅: 3.5 mm, 4.5 mm	**Equivalent** Subject device diameters are within the range of diameters of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
Gingival Height	NP – 0.5, 1, 2, 2.3, 3, 4 & 5 mm SP – 1, 2, 2.3, 3, 4 & 5 mm	Straight: 0.8 to 6.5 mm Angled: 1.5 to 3.5 mm	**Equivalent** Subject devices are included in the range of the predicate device gingival heights or higher. Higher gingival height do not represent a worst case in terms of performance.
Angulation	0°, 17° & 30°	0°, 17° & 30°	**Same**
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined and anodized (only NP platform)	Machined	**Equivalent** Anodized surface treatment is presented in other abutments of K101945.
Single Use	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**
Cement Retained Abutments (Straight, Angled & Customizable)			
Principal of operation	Abutment designed to accept a cement-retained prosthetic. Customizable Cement Retained Abutment designed to accept a cement-retained prosthetic. Features to facilitate trimming height of coronal geometry from 6 mm down to a minimum of 4 mm.	To support final restorations when placed on implants.	**Equivalent** The principal of operation of subject device is within of the primary predicate device. These devices are equivalent in design to the subject straight Cement-Retained Abutments described above. The ability to modify the abutment height does not affect the intended use. The length of the combination of the abutment and the cemented prosthesis will be equivalent to the straight Cement-Retained Abutments.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Indexed	Both Indexed and Non-indexed	**Same**
Diameter	Platform ∅: NP – 3.5 mm SP – 4.5 mm	Platform ∅: 3.5 mm, 4.5 mm	**Same**

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Gingival Height	Straight – 0.5, 1. 2, 1.5 & 3 mm 17° - 1.5 & 3 mm 25° - 2 & 3 mm	Straight - 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 & 6.5 mm Angled - 1.5, 2.5 & 3.5 mm	**Equivalent** Subject device are included in the range of the predicate device gingival heights.
Angulation	0°, 17° & 25°	0°, 17° & 30°	**Equivalent** The subject devices are included in the range of the predicate device angulation.
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined and anodized (only NP platform)	Machined	**Equivalent** Anodized surface treatment is presented in other abutments of K101945.
Single Use	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**

Table 4: Substantial Equivalence Comparison – Technological characteristics – Traditional Abutments (Titanium Temporary abutment)

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K191191** Neodent Implant System – Temporary Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Titanium Temporary	**Titanium Temporary Abutment for Crown and for Bridge**	**GM Temporary Abutment**	
Principal of operation	Abutment for the creation of a temporary, non-occlusal restoration to address esthetics during fabrication of final prosthesis.	Abutment for the creation of a temporary, non-occlusal restoration to address esthetics during fabrication of final prosthesis.	**Same** The principal of operation of subject device is the same of the primary predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Both Indexed and Non-indexed	Both Indexed and Non-indexed	**Same**
Diameter	Platform ∅: NP – 3.5 mm SP – 4.5 & 5.5 mm	Platform ∅: 3.5 mm, 4.5 mm	**Equivalent** Subject device diameters are within the range of diameters of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
Gingival Height	1.0 mm	0.8; 1.5; 2.5 and 3.5 mm	**Equivalent** Subject device are included in the range of the predicate device gingival heights.
Angulation	Straight	Straight	**Same**
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined (SP platform) Machined and anodized (NP platform)	Machined	**Equivalent** Anodized surface treatment is presented in other abutments of primary predicate device K101945.
Duration of Use	Up to 6 months	Up to 6 months	**Same**
Single Use	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**

Table 5: Substantial Equivalence Comparison – Technological characteristics – Traditional Abutments (Equator Attachment and Removable Prosthesis Attachment)

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATES		EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190040** Straumann BLX Line Extension - New Abutments Institut Straumann AG	
Equator Attachment	**Equator Attachment IF**	**CM Mini Ball Attachment**	**GM Attachment Equator**	**Novaloc Abutments**	
Principal of operation	Abutment to accept detachable over-denture prostheses. **Coronal Geometry**: To accept o-ring style matrices	Abutment to accept detachable over-denture prostheses. **Coronal Geometry**: To accept o-ring style matrices	Abutment to accept detachable over-denture prostheses. **Coronal Geometry:** To accept o-ring style matrices		**Same** The principal of operation of subject device is the same of the primary predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	Cone Morse		**Equivalent** The implant-to-abutment interface is equivalent to that of the reference predicate. Dynamic fatigue testing is provided to support the performance of the subject Internal Hex interface.
Indexing	Non-indexed	Non-indexed	Non-indexed		**Same**
Diameter	Platform ∅: NP – 3.5 mm SP – 4.5	Not Defined	Platform ∅: 3.5 to 5.0 mm		**Equivalent** Subject devices are within the range of reference predicate devices diameters.
Gingival Height	NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm	1.5, 2.5, 3.5, 4.5 & 5.5 mm	1.5, 2.5, 3.5 ,4.5 & 5.5mm		**Equivalent** Subject devices are included in the range of the predicate devices gingival heights.
Angulation	Straight	Straight	Straight		**Same**
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)		**Same**
Surface Treatment	Machined with titanium nitride coating	Machined	Machined with titanium nitride coating		**Equivalent** Subject devices and reference predicate devices have the same surface treatment
Single Use	Yes	Yes	Yes		**Same**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$		**Same**

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATES		EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190040** Straumann BLX Line Extension - New Abutments Institut Straumann AG	
Removable Prosthesis Attachment	**Removable Prosthesis Attachment IF**	**CM Mini Ball Attachment**	**GM Attachment Equator**	**Novaloc Abutments**	
Principal of operation	Abutment to accept detachable over-denture prostheses.	Abutment to accept detachable over-denture prostheses.	Abutment to accept detachable over-denture prostheses.	Abutment to accept detachable over-denture prostheses.	**Same** The principal of operation of subject device is the same of the primary predicate device.
Design	**Coronal Geometry**: To accept Valoc Novaloc matrices	**Coronal Geometry**: To accept o-ring style matrices	**Coronal Geometry:** To accept o-ring style matrices	**Coronal Geometry:** To accept Valoc Novaloc matrices	**Equivalent** Subject devices and reference predicates per K190040 have same intended use and similar coronal geometry (differing gingival heights are not significant to performance).
Implant-to-Abutment Interface	Internal Hex	Cone Morse	Cone Morse	Straumann BLX	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Non-indexed	Non-indexed	Non-indexed	Indexed	**Same**
Diameter	Platform ∅: NP – 3.5 mm SP – 4.5	Not Defined	Platform ∅: 3.5 to 5.0 mm	4.5 mm	**Equivalent** Subject devices are within the range of reference predicate devices diameters.
Gingival Height	NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm	1.5, 2.5, 3.5, 4.5 & 5.5 mm	1.5, 2.5, 3.5 ,4.5 & 5.5mm	1.5 to 6.5 mm	**Equivalent** Subject devices are included in the range of the predicate devices gingival heights.
Angulation	Straight	Straight	Straight	Straight and Angulated	**Same**
Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined and titanium nitride coating		Machined and titanium nitride coating	Machined and titanium nitride coating	**Equivalent** Subject devices and reference predicate devices have the same surface treatment
Single Use	Yes	Yes	Yes	Yes	**Same**

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATES		EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190040** Straumann BLX Line Extension - New Abutments Institut Straumann AG	
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	Non-Sterile	**Same**

Table 6: Substantial Equivalence Comparison – Technological characteristics – Traditional Abutments (UCLA CoCr)

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	PRIMARY PREDICATE **K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K173902** Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
UCLA CoCr	**UCLA CoCr IF**	**Not applicable**	**GM Exact Co-Cr Abutment for Crown**	
Principal of operation	Abutment to facilitate the casting of base metal and precious metal alloy prostheses.		Abutment to facilitate the casting of base metal and precious metal alloy prostheses.	**Same** The principal of operation of subject device is the same of the reference predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Both Indexed and Non-indexed		Non-indexed	**Equivalent** The subject devices indexing is the equivalent of reference predicate devices. The indexed devices are presented in other primary predicate devices.
Diameter	Platform ∅: NP – 3.5 mm SP – 4.5 & 5.5 mm		Platform ∅: 3.5 to 6.0 mm	**Equivalent** Subject devices are within the range of reference predicate devices diameters.
Gingival Height	NP – 1, 2, 3, 4 & 5 mm SP – 1, 2, 3, 4 & 5 mm		1 mm	**Equivalent** The different gingival heights do not introduce a new worst in terms of performance.
Angulation	Straight		Straight	**Same** The subject devices and the predicate devices are straight.
Material	CoCr Alloy with POM polymer		CoCr Alloy with POM polymer	**Same** Subject, primary and reference predicate devices have the same material of construction.
Surface Treatment	Machined and anodized (only NP platform)		Machined	**Same** Anodized surface treatment is presented in other abutments of primary predicate device K101945.
Single Use	Yes	Yes	Yes	**Same**

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Alvim Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K173902** Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Sterilization Method	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}.	**Same** Subject and reference predicate devices utilize the same sterilization method and minimum SAL.

Table 7: Substantial Equivalence Comparison – CADCAM Abutments (Anti-Rotational Titanium Base IF)

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATES		EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150367 & K153624** 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.	
Anti-Rotational Titanium Base IF	**Anti-Rotational Titanium Base IF**	**Titanium Base Abutment**	**GM Exact Titanium Base**	
Principal of operation	Abutment designed to accept a cement-retained prosthetic. Titanium Base abutments are two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.	Abutment designed to accept a cement-retained single or multi-unit restorations, or screw-retained single restorations. Titanium Base abutments as two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.	Screw-retained single-unit, or Cement-retained single or multi-unit. Titanium Base abutments as two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.	**Equivalent** The principal of operation of subject device is within the reference predicate devices.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Indexed	Indexed	Indexed	**Same**
Diameter	Platform ∅: NP – 3.5 SP – 4.5 & 5.5 mm	Platform ∅: 3.5 mm, 4.5 mm	Platform ∅: 5.5 mm	**Equivalent** Subject device diameters are within the range of diameters of the predicate devices.
Gingival Height	NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm	0.8, 1.5, 2.5, 3.5 & 4.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm	**Equivalent** Subject devices are included in the range of the predicate device gingival heights.
Angulation	Straight	Straight	Straight	**Same**
CAD/CAM Restoration Angulation	Up to 30°	Up to 30°	Up to 30°	**Same**
CAM/CAM Material superstructure	IPS e.max CAD Coron (CoCr) Zerion LT	IPS e.max CAD Cobalt-chromium Zirconia	IPS e.max CAD Cobalt-chromium Zirconia	**Equivalent** The top-half material indicated for subject device and reference predicate device are the same.
Abutment Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATES		EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K150367 & K153624** 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.	
Surface Treatment	Machined (SP platform) Machined and anodized (NP platform)	Machined		**Equivalent** Anodized surface treatment is presented in other abutments of K101945.
Single Use	Yes	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**

Table 8: Substantial Equivalence Comparison – CADCAM Abutments (Rotational Titanium Base IF)

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K192229** Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
Rotational Titanium Base IF	**Rotational Titanium Base IF**	**GM Titanium Base for Bridge**	
Principal of operation	Abutment designed to accept a cement or screw-retained prosthetic. Titanium Base abutments as two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.	Abutment designed to accept a cement or screw-retained prosthetic. Titanium Base abutments as two-piece abutments which are composed of a titanium base and a patient-specific CAD/CAM top-half, that when assembled together form the final finished device.	**Same**
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Non-Indexed	Non-Indexed	**Same**
Diameter	Platform ∅: NP – 3.5 SP – 4.5 & 5.5 mm	Platform ∅: 3.5, 4.5, and 5.5 mm	**Equivalent** Subject device diameters are within the range of diameters of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
Gingival Height	NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm	0.8, 1.5, 2.5, 3.5 & 4.5 mm	**Equivalent** Subject devices are included in the range of the predicate device gingival heights.
Angulation	Straight	Straight	**Same**
CAD/CAM Restoration Angulation	Up to 30°	Up to 30°	**Same**
CAM/CAM material superstructure	Titanium (brand name (ticon) Cobalt-chromium (brand name coron) Zirconia (brand name zerion LT)	Titanium (brand name ticon) Cobalt-chromium (brand name coron) Zirconia (brand name zerion LT)	**Same**
Abutment Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined and anodized (only NP platform)	Machined	**Equivalent** Anodized surface treatment is presented in other abutments of K101945.
Single Use	Yes	Yes	**Same**

COMPARISON	SUBJECT DEVICES	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	K193234 NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192229** Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**

Table 9: Substantial Equivalence Comparison – CADCAM Abutments (CARES® Abutment IF)

COMPARISON	SUBJECT DEVICES **K193234** NUVO IF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	REFERENCE PREDICATE **K150367** Neodent Implant System – Titanium Base & Preface JJGC Indústria e Comércio de Materiais Dentários S.A.	EQUIVALENCE DISCUSSION
CARES® Abutment IF	**CARES® Abutment IF**	**PreFace Abutment**	
Principal of operation	Milling blank with the Implant-to-Abutment interface pre-milled 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 pre-milled at one end. Used to fabricate patient-specific abutments that are indicated with screw-retained single restorations or cement-retained single or multi-unit restorations.	**Equivalent** The principal of operation of subject device is with the reference predicate device.
Implant-to-Abutment Interface	Internal Hex	Cone Morse	**Equivalent** The implant interface is equivalent to that of the predicate.
Indexing	Indexed	Indexed	**Same**
Diameter	Oversize cylinder for milling 11.5 mm & 15.8 mm diameters Platform ∅: NP – 3.5 SP – 4.5	Oversize cylinder for milling 11.5 mm & 15.8 mm diameters Platform ∅: Not defined	**Same**
Gingival Height	NP – 0.5, 1 & 3 mm SP – 0.5, 1 & 3 mm	0.8, 1.5, 2.5, 3.5 & 4.5 mm	**Equivalent** Subject devices are included in the range of the predicate device gingival heights.
Angulation	Straight Angulation of milled abutment: up to 30°	Straight Angulation of milled abutment: up to 30°	**Same**
Abutment Material	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	**Same**
Surface Treatment	Machined (SP platform) Machined and anodized (NP platform)	Machined	**Equivalent** Anodized surface treatment is presented in other abutments of K101945.
Single Use	Yes	Yes	**Same**
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 $1x10^{-6}$	**Same**

PERFORMANCE DATA

Dynamic fatigue test per ISO 14801 and FDA guidance entitled *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, issued on: May 12, 2004, was performed to determine the fatigue strength for the worst-case constructs assembled using the subject devices.

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 x 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 x 10^{-6} has been validated.

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

Sterilization of the subject abutments via moist heat was validated per ISO 17665-1 and ISO 17665-2. A minimum Sterility Assurance Level (SAL) of 1 x 10-6 has been validated.

Biological Safety Assessment guided by ISO 10993-1 and FDA guidance entitled *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*, issued June 16, 2016. Reference to previous biocompatibility testing is supplied as follows:

- Cytotoxicity testing was performed per ISO 10993-5.
- Chemical characterization was performed per ISO 10993-18.

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

Product and package stability has been validated per ASTM F1980.

Product endotoxin testing (LAL) is performed monthly on products representative of the subject devices per ANSI/AAMI ST72.

CONCLUSION

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