February 13, 2020

Implacil de Bortoli Material Odontologico Ltda
c/o Janine Treter
Regulatory Affairs Specialist
PR Serviços Regulatórios Administrativos Ltda
Rua Alice Além Saadi, 855/ 2402
Ribeirão Preto, São Paulo 14096-570
BRAZIL

Re: K183024
Trade/Device Name: Implacil Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 13, 2020
Received: January 16, 2020

Dear Janine Treter:

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,

Srinivas “Nandu” 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)*
K183024

Device Name

Implacil Implant System

Indications for Use *(Describe)*
Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit and/or multi-unit restorations. When a one-stage surgical approach is applied, the Implacil Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	Implacil de Bortoli Material Odontologico Ltda Rua Vicente de Carvalho 178-182 São Paulo, São Paulo, Brazil 01521020
Contact Person and Preparer	Janine Treter, PhD Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: janine@rapassarini.com.br Telephone +55 (47) 3804 0075
Date Prepared	13/Feb/2020

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Implacil Implant System
Common Name	Dental implant and abutment
Primary Classification Name	Endosseous dental implant
Primary Classification Regulation	21 CFR 872.3640, Class II
Primary Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K170398 – S.I.N. Dental Implant System – S.I.N. Sistema de Implante Nacional S.A.
Reference Devices	K062931 – IMPLUS - LEADER Italia S.R.O K072642 - BIOMET 3i Dental Abutments and Restorative Components - Biomet 3i, Inc. K090452 - Neoss Implant System 03,25 - Neoss Limited K101207 - Neodent Implant System -JJGC Industria e Comercio de Materiais Dentarios S.A. K101945- Neodent Implant System - JJGC Industria e Comercio de Materiais Dentarios S.A.

K133510 - Neodent Implant System - JJGC Industria e Comercio de Materiais Dentarios S.A.
K140440 - Noris Medical Dental Implants System - Noris Medical, Ltd.
K163060 -Deep Conical (DC) Implants and Accessories - Southern Implants (Pty) Ltd
K163634 - External Hex Implants - Southern Implants (Pty) Ltd
K170392 – S.I.N. Dental Implant System – S.I.N. Sistema de Implante Nacional S.A.
K170608 - UF(II) Implant System - DIO Corporation
K173819 – MyPlant II Implant System Hager & Meisinger GmbH
K173902 - Neodent Implant System - GM Line - JJGC Industria e Comercio de Materiais Dentarios S.A.
K180282 - MIS Internal Hex Dental Implant System -MIS Implants Technologies Ltd.

INDICATIONS FOR USE

Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit and/or multi-unit restorations. When a one-stage surgical approach is applied, the Implacil Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

Implacil Implant System is composed of three implant lines that are divided according to the implant-to-abutment interface: External Hex (HE), Internal Hex (HI) and Morse Taper AR Due Cone (CM AR). HE and HI lines are composed of tissue-level implants while CM AR line of bone-level implants. Each implant line is composed of implants and related prosthetic components available in multiple designs (temporary, screwed, cementable, angled, straight, UCLA, ball).

HE implant line implants are available in two root-forms designs: conical (tapered) and cylindrical. Conical implants are available in three diameters and platforms (3.5, 4.0 and 5.0 mm) and five lengths (7.0, 9.0, 11.0, 13.0 and 15.0 mm). Cylindrical implants are provided in four diameters (3.3, 3.75, 4.0 and 4.75 mm), three platforms (3.5, 4.0 and 5.0 mm) and five lengths (8.0, 10.0, 11.5, 13.0 and 15.0 mm). HE cylindrical implants of diameters 3.75 and 4.0 share the same platform of 4.0 mm.

HI implant line implants are available in two root-forms designs: conical (tapered) and cylindrical. Conical implants are available in three diameters and platforms (3.5, 4.0 and 5.0 mm). For diameters 3.5 and 4.0 are available in the lengths 8.0, 9.0, 11.0, 13.0 and 15.0 mm, and for diameters 5.0 are available in the lengths 7.0, 9.0, 11.0, 13.0 and 15.0 mm. Cylindrical implants are provided in four diameters (3.3, 3.75, 4.3 and 4.75 mm) and three platforms (3.5, 4.0 and 5.0 mm). For diameter 3.3 are available in the lengths 8.0, 9.0, 11.0, 13.0 and 15.0 mm, and for diameters 3.75 and 4.3 are available in the lengths 7.0, 9.0, 11.0, 13.0 and 15.0 mm. HI cylindrical implants of diameters 3.75 and 4.3 share the same platform of 4.0 mm.

CM AR implant line implants are available in conical root-form design only, in four diameters (3.5, 4.0, 4.5 and 5.0 mm) and five lengths (7.0, 9.0, 11.0, 13.0 and 15.0 mm).

Implacil implants are made of commercially pure titanium (ASTM F67). Implacil prosthetic components are made of commercially pure titanium (ASTM F67) or titanium alloy (ASTM F136). Implacil Implant System screws (abutment screw, UCLA screws and coping screws) are made of titanium alloy (ASTM F136).

The subject device abutments components mate exclusively with the subject implants of the same line (HI, HE, CM AR).

TECHNOLOGICAL CHARACTERISTICS

The subject device and the predicate devices have the same intended use as and technological characteristics as shown in the tables below. Differences in the design features between the subject devices and the primary predicate device K170398 are addressed by comparison to the reference devices.

Table 5.1: Comparison on indication for use statement

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT
SUBJECT DEVICE	**K183024** – Implacil Implant System I mplacil de Bortoli Material Odontologico Ltda	Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit and/or multi-unit restorations. When a one-stage surgical approach is applied, the Implacil Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
PRIMARY PREDICATE DEVICE	**K170398** - S.I.N. Dental Implant System S.I.N. Sistema de Implante Nacional S.A	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Revolution Compact with a 6 mm length is intended for delayed loading only.
REFERENCE DEVICES	**K062931** – IMPLUS LEADER Italia S.R.O	IMPLUS implant fixtures are intended to be surgically placed in the bone of the mandibular and/or maxillary dental arches in order to provide support for fixed and/or removal prosthetics in order to restore original features and masticatory functions. Implus implant fixtures are indicated for permanent use. Implus implant fixtures are disposable and are for one-time use only. These fixtures are not to be recleaned or re-sterilized.
	K072642 – BIOMET 3i Dental Abutments and Restorative Components Biomet 3i, Inc.	BIOMET 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. Restorative Components * Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing. * Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. * Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.
	K090452 – Neoss Implant System 03,25 Neoss Ltd	The Neoss Implant System 03,25 is for single-stage and two-stage surgical procedures and cement or screw retained restorations. The Neoss Implant System 03,25 are intended for immediate loading on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar. The Neoss Implant 03,25 abutments are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.
	K101207 - Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios S.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.

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT
REFERENCE DEVICES	**K101945**- Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios S.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.
	K133510 - Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios S.A.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lowerjaw 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.
	K163060 -Deep Conical (DC) Implants and Accessories Southern Implants (Pty) Ltd	Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors
	K163634 - External Hex Implants Southern Implants (Pty) Ltd	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.
	K170608 - UF(II) Implant System DIO Corporation	The UF(II) Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The UF(II) Implant System(Ø3.8 ~ Ø5.5) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading.
	K170392 - S.I.N. Dental Implant System S.I.N. Sistema de Implante Nacional S.A	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7 mm are intended for delayed loading only.
	K173819 – MyPlant II Implant System Hager & Meisinger GmbH	The MyPlant II implants are surgically placed in the maxilla or mandible to enable prosthetic restorations in edentulous or partially edentulous patients. The implants are to be used exclusively with MyPlant II abutments and prosthetic components. The abutments serve for prosthetic restorations and can include individual crowns, bridges, partial or full prostheses. Abutments can be used for single tooth restorations or for the restoration of several teeth. The implants are intended for delayed loading with two surgical interventions. In case of appropriate primary stability (35 Ncm), immediate temporary restoration with appropriate occlusal load can also be performed.

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT
REFERENCE DEVICES	**K173902 -** Neodent Implant System - GM Line JJGC Industria e Comercio de Materiais Dentarios S.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.
	K180282 - MIS Internal Hex Dental Implant System MIS Implants Technologies Ltd.	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

Table 5.2: SE comparison on HE implants

Trade Name Information	**SUBJECT DEVICES**	**PRIMARY PREDICATE DEVICE**	**REFERENCE DEVICES**		
	K183024 – Implacil Implant System	**K170398** - S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K062931** - IMPLUS	**K163634 - -** External Hex Implants
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	LEADER Italia S.R.O.	Southern Implants (Pty) Ltd. November 6, 2017
Implant-to-abutment connection	HE interface	HE interface	HE interface	HE interface	HE interface
Raw Material	CPTi	CPTi	CPTi	CPTi	CPTi
Surface	Grit-blasted and acid-etched	Acid-etched and HA	Grit-blasted and acid-etched	Sand-blasted and acid-etched	Grit-blasted and acid-etched Machine collar versions available
Root type design	Cylindrical Tapered	Cylindrical	Cylindrical Tapered	Cylindrical Tapered	Cylindrical Tapered
Implant diameter (mm)	Cylindrical: **3.3:** 8, 10, 11.5, 13, 15 **3.75:** 8, 10, 11.5, 13, 15 **4.0:** 8, 10, 11.5, 13, 15 **4.75:** 8, 10, 11.5, 13, 15 Tapered: **3.5:** 7, 9, 11, 13, 15 **4.0:** 7, 9, 11, 13, 15 **5.0:** 7, 9, 11, 13, 15	Cylindrical: **3.25:** 8.5, 10, 11.5, 13, 15 **3.5**: 7, 8.5, 10, 11.5, 13, 15 **3.75:** 7, 8.5, 10, 11.5, 13, 15 **4.0:** 6, 7, 8.5, 10, 11.5, 13, 15 4.5: 8.5, 10, 11.5, 13, 15 **5.0:** 6, 7, 8.5, 10, 11.5, 13, 15	Cylindrical: **3.3:** 9, 11, 13, 15, 17 **3.75:** 9, 11, 13, 15, 17, 19 **4.0:** 9, 11, 13, 15, 17, 19 **4.5:** 9, 11, 13 **5.0: 7,** 9, 11, 13 Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16	Cylindrical: **3.3:** 10, 11.5, 13, 15 **3.75:** 8, 10, 11.5, 13, 15, 18, 20 **5.0:** 8, 10, 11.5, 13 Tapered: **4.0**: 8, 10, 11.5, 13, 15 **5.0**: 8, 10, 11.5, 13	Cylindrical: **3.75:** 7, 8.5, 10, 11.5, 13, 15, 18, 20 **5.0:** 6, 7, 8.5, 10, 11.5, 13, 15 **6.0:** 7, 8.5, 10, 11.5, 13, 15 Tapered: **3.25**: 8.5, 10, 11.5, 13, 15, 18 **4.0**: 6, 8.5, 10, 11.5, 13, 15 **4.7**: 10, 11.5, 13, 15, 18 **5.0**: 6, 8.5, 10, 11.5, 13, 15 **5.7**: 10, 11.5, 13, 15, 18
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.3: SE comparison on HI implants

Trade Name Information	**SUBJECT DEVICES**	**PRIMARY PREDICATE DEVICE**	**REFERENCE DEVICES**	
	K183024 – Implacil Implant System	**K170398** - S.I.N. Dental Implant System	**K062931 -** IMPLUS	**K180282 -** MIS Internal Hex Dental Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	LEADER Italia S.R.O.	MIS Implants Technologies Ltd.
Implant-to-abutment connection	HI interface	HI interface	HI interface	HI interface
Raw Material	CPTi	CPTi	CPTi	Ti alloy (TI-6Al-4V ELI)
Surface	Grit-blasted and acid-etched	Acid-etched and HA	Sand-blasted and acid-etched	Anodized, sand blasted and acid etched Sand blasted and acid etched
Root type design	Cylindrical Tapered	Cylindrical	Cylindrical Tapered	Cylindrical Tapered
Diameter: length (mm)	<u>Cylindrical</u> **3.3**: 8, 9, 11, 13, 15 **3.75**: 7, 9, 11, 13, 15 **4.3**: 7, 9, 11, 13, 15 **4.75**: 7, 9, 11, 13, 15 <u>Tapered:</u> **3.5**: 8, 9, 11, 13, 15 **4.0**: 8, 9, 11, 13, 15 **5.0**: 7, 9, 11, 13, 15	<u>Cylindrical</u> **3.8**: 8.5, 10, 11.5, 13, 15 **4.5**: 8.5, 10, 11.5, 13, 15 **5.0**: 8.5, 10, 11.5, 13, 15	<u>Cylindrical</u> **3.3**: 8, 10, 11.5, 13, 16 **3.75**: 8, 10, 11.5, 13, 16 **4.5**: 8, 10, 11.5, 13, 16 **5.5**: 8, 10, 11.5, 13 <u>Tapered:</u> **4.0**: 8, 10, 11.5, 13, 16 **5.0**: 8, 10, 11.5, 13, 16 **6.0**: 8, 10, 11.5, 13	<u>Cylindrical</u> **3.3**: 10, 11.5, 13, 16 **3.75**: 8, 10, 11.5, 13, 16, 18, 20 **4.2**: 6, 8, 10, 11.5, 13, 16, 18, 20 **5.0**: 6, 8, 10, 11.5, 13, 16 **6.0**: 6, 8, 10, 11.5, 13 <u>Tapered:</u> **3.3**: 10, 11.5, 13, 16 **3.75**: 8, 10, 11.5, 13, 16, 18, 20 **4.2**: 8, 10, 11.5, 13, 16, 18, 20 **5.0**: 8, 10, 11.5, 13, 16 **6.0**: 8, 10, 11.5, 13
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.4: SE comparison on CM AR implants

Trade Name Information	**SUBJECT DEVICES**	**REFERENCE DEVICES**		
	K183024 – Implacil Implant System	**K101945** – Neodent Implant System	**K170608** – UF(II) Implant System	**K163060 -**Deep Conical (DC) Implants and Accessories
	Implacil de Bortoli Material Odontologico Ltda	JJGC Industria e Comercio de Materiais Dentarios S.A.	DIO Corporation	Southern Implants (Pty) Ltd
Implant-to-abutment connection	Conical connection (CM AR)	Conical connection (CM)	Conical connection (CM)	Conical connection (Deep Conical)
Raw Material	CPTi	CPTi	CPTi	CPTi
Surface	Grit-blasted and acid-etched	Grit-blasted and acid-etched	Hybrid Sand-blasted and acid-etched	Roughened surface
Root type design	Tapered	Cylindrical Tapered	Tapered	Cylindrical Tapered
Implant-to-abutment indexation feature	Dodecagon (double-hexagon)	Hexagon	Hexagon	Dodecagon (double-hexagon)
Implant diameter: lenghts (mm)	<u>Tapered:</u> **3.5:** 7, 9, 11, 13, 15 **4.0**: 7, 9, 11, 13, 15 **4.5:** 7, 9, 11, 13, 15 **5.0:** 7, 9, 11, 13, 15	<u>Cylindrical:</u> **3.5:** 7, 8, 9, 11, 13, 15, 17 **3.75**: 7, 8, 9, 11, 13, 15, 17 **4.0:** 7, 8, 9, 11, 13, 15, 17, 19 **5.0:** 7, 8, 9, 11, 13 <u>Tapered:</u> **3.5:** 8, 10, 11.5, 13, 16 **4.3**: 8, 10, 11.5, 13, 16 **5.0**: 8, 10, 11.5, 13, 16	<u>Tapered:</u> **3.8:** 8.5, 10, 11.5, 13, 15, 16 **4.0:** 8.5, 10, 11.5, 13, 15, 16 **4.5**: 7, 8.5, 10, 11.5, 13, 15, 16 **5.0**: 7, 8.5, 10, 11.5, 13, 15, 16 **5.5**: 7, 8.5, 10, 11.5, 13, 15, 16	<u>Cylindrical:</u> **3.0:** 11, 13, 15 **3.5:** 8, 9, 11, 13, 15 **4.0:** 6, 8, 9, 11, 13, 15 **5.0:** 9, 11, 13, 15 <u>Tapered:</u> **3.0:** 9, 11, 13, 15 **3.5:** 8, 9, 11, 13, 15 **4.0:** 6, 8, 9, 11, 13, 15 **5.0:** 9, 11, 13, 15
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.5: SE comparison on Covers

Trade Name Information	**SUBJECT DEVICES**	**REFERENCE DEVICES**			
	K183024 – Implacil Implant System	**K101207** – Neodent Implant System	**K180282 -** MIS Internal Hex Dental Implant System	**K101945** – Neodent Implant System	**K170608** – UF(II) Implant System
	Implacil de Bortoli Material Odontologico Ltda	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	JJGC Industria e Comercio de Materiais Dentarios S.A.	DIO Corporation
Implant-to-abutment connection (Implant line)	HE interface HI interface Conical interface (CM AR)	HE interface	HI interface	Conical interface (CM)	Conical interface (CM)
Diameter (mm)	HE: 3.5, 4.0, 5.0 HI: 3.5, 4.0, 5.0 CM AR: 2.5	HE: 3.3, 4.1, 4.3, 5.0	HI: 3.3, 3.75, 4.7	CM: 2.5	CM: 2.7, 2.794, 3.6, 3.8
Gingival Height (mm)	HE: 0 HI: 0 CM AR: 2	HE: 0	HI: 0	CM: 0, 2	CM: 0, 1, 2, 3
Raw material	CPTi	Ti alloy	Ti alloy	Ti alloy	CPTi
Surface	Machined	Machined	Machined and Anodized	Machined	Machined and anodized
Angulation	0°	0°	0°	0°	0°
Load	No occlusal load	No occlusal load	No occlusal load	No occlusal load	No occlusal load
Sterility	Provided sterile by irradiation.	Provided sterile by ethylene oxide.	Provided sterile by irradiation	Provided sterile by ethylene oxide.	Provided sterile by irradiation.

Table 5.6: SE comparison on Healing Abutments

Trade Name Information	**SUBJECT DEVICES**	**PRIMARY PREDICATE DEVICES**	**REFERENCE DEVICES**		
	K183024 – Implacil Implant System	**K170398** - S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K180282 -** MIS Internal Hex Dental Implant System	**K101945** – Neodent Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	JJGC Industria e Comercio de Materiais Dentarios S.A.
Implant-to-abutment connection	HE interface HI interface Conical interface (CM AR)	HE interface HI interface	HE interface	HI interface	Conical interface (CM)
Diameter (mm)	HE: 3.5, 4.0, 5.0 HI: 3.5, 4.0, 5.0 CM AR: 3.5, 4.5	HE: 3.6, 4.1, 5.0	HE: 3.3, 4.1, 4.3, 5.0	HI: 4.0, 4.3, 4.8, 5.0, 5.5, 6.5	CM: 3.5, 4.0
Gingival Height (mm)	HE: 2, 3, 4, 5, 6, 7 HI: 2, 3, 4, 5, 6, 7 CM AR: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5	HE: 1, 2, 4, 6, 8	HE: 2, 3, 4, 5, 6	HI: 2, 3, 4, 5, 6, 8	CM: 0.8, 3.5, 4.5, 5.5, 6.5
Raw material	CPTi	Ti alloy	Ti alloy	Ti alloy	Ti alloy
Surface	Machined	Machined	Machined	Machined and Anodized	Machined
Angulation	0°	0°	0°	0°	0°
Load	No occlusal load	No occlusal load	No occlusal load	No occlusal load	No occlusal load
Sterility	Provided sterile by irradiation.	Provided sterile by irradiation.	Provided sterile by ethylene oxide.	Provided sterile by irradiation	Provided sterile by ethylene oxide.

Table 5.7: SE comparison on Healing Abutment Covers

Trade Name Information	**SUBJECT DEVICES**	**PRIMARY PREDICATE DEVICES**	**REFERENCE DEVICES**	
	K183024 – Implacil Implant System	**K170398** - S.I.N. Dental Implant System	**K180282 –** MIS Internal Hex Dental Implant System	**K170392** - S.I.N. Dental Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	MIS Implants Technologies Ltd.	S.I.N. Sistema de Implante Nacional S.A.
Implant-to-abutment connection	Not applicable (is mounted on the abutment)	Not applicable (is mounted on the abutment)	Not applicable (is mounted on the abutment)	Not applicable (is mounted on the abutment)
Diameter (mm)	3.8, 4.5, 4.8	4.8	4.8	3.3
Total height (mm)	5.5, 5.8, 7.5	5	4.3	Unknown
Raw material	CPTi	Ti alloy	CPTi	Ti alloy
Surface	Machined	Machined	Machined	Machined
Angulation	0°	0°	0°	0°
Load	No occlusal load	No occlusal load	No occlusal load	No occlusal load
Sterility	Provided non-sterile. Steam sterilized prior use.	Provided sterile by irradiation.	Provided sterile by irradiation	Provided sterile by irradiation.

Table 5.8: SE comparison on Tapered Aesthetic Abutments

Trade Name Information	**SUBJECT DEVICES**	**REFERENCE DEVICE**						
	K183024 – Implacil Implant System	**K101207** – Neodent Implant System	**K133510** – Neodent Implant System	**K062931** - IMPLUS	**K072642** - BIOMET 3i Dental Abutments and Restorative Components	**K180282 –** MIS Internal Hex Dental Implant System	**K101945** – Neodent Implant System	**K170608** – UF(II) Implant System
	Implacil de Bortoli Material Odontologico Ltda	JJGC Industria e Comercio de Materiais Dentarios S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	LEADER Italia S.R.O.	Biomet 3i, Inc.	MIS Implants Technologies Ltd.	JJGC Industria e Comercio de Materiais Dentarios S.A.	DIO Corporation
Implant-to-abutment connection	HE interface HI interface Conical interface (CM AR)	HE interface	HE interface	HE interface	HI interface	HI interface	Conical interface (CM)	Conical interface (CM)
Diameter (mm)	HE: 3.5, 4.0, 5.0 HI: 3.5, 4.0, 5.0 CM AR: 4.8	HE: 4.1, 4.3, 5.0	HE: 3.3	HE: 4.1	HI: 3.4, 5.0, 6.0	HI: 4.8	CM: 4.8	CM: 4.8
Gingival height (mm)	HE: 1, 2, 3 HI: 1, 2, 3 CM: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5	HE: 1, 2, 3	HE: 1, 2, 3	HE: 1, 2, 3	HI: 1, 2, 3, 4, 5.5	HI: 1, 2, 3, 4, 5	CM: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5, 6.5	Unknown
Anti-rotational feature	Yes	No	No	No	No	No	No	No
Raw material	CPTi	Ti alloy	Ti alloy	Ti alloy	Ti alloy	Ti alloy	Ti alloy	CPTi
Surface	Machined	Machined	Machined	Machined/TiN	Machined	Machined	Machined	Machined
Angulation	0, 17, 30°	0°	0°	0, 17°	0, 17, 25°	0, 15, 25°	0, 17, 30°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by ethylene oxide.	Provided sterile by ethylene oxide.	Unknown	Provided sterile. Unknown method	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.

Table 5.9: SE comparison on Mini Tapered and Mini Tapered Fit Abutments

Trade Name Information	**SUBJECT DEVICES**	**REFERENCE DEVICE**				
	K183024 – Implacil Implant System	**K101207** – Neodent Implant System	**K180282 –** MIS Internal Hex Dental Implant System	**K072642 -** BIOMET 3i Dental Abutments and Restorative Components	**K101945** – Neodent Implant System	**K170608** – UF(II) Implant System
	Implacil de Bortoli Material Odontologico Ltda	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	Biomet 3i, Inc.	JJGC Industria e Comercio de Materiais Dentarios S.A.	DIO Corporation
Implant-to-abutment connection	HE interface HI interface Conical interface (CM AR)	HE interface	HI interface	HI interface	Conical interface (CM)	Conical interface (CM)
Diameter (mm)	HE: 3.5, 4.0, 5.0 HI: 3.5, 4.0, 5.0 CM AR: 4.8	HE: 4.1, 4.3, 5.0	HI: 4.8	HI: 3.4, 5.0, 6.0	CM: 4.5	CM: 4.8
Gingival height (mm)	HE: 1, 2, 3 HI: 1, 2, 3 CM AR: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5	HE: 1, 2, 3, 4,	HI: 1, 2, 3	HI: 1, 2, 3, 4, 5.5	CM: 1.5, 2.5, 3.5	Unknown
Anti-rotational feature	Yes	No	No	No	Yes	No
Raw material	CPTi Ti alloy	Ti alloy	Ti alloy	Ti alloy	Ti alloy	CPTi
Surface	Machined	Machined	Machined/ Anodized	Machined	Machined	Machined
Angulation	0, 17, 30°	0°	0, 17, 30°	0, 15°	0, 17, 30°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.	Provided sterile. Unknown method	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.

Table 5.10: SE comparison on Abutments and Abutment with Collar

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES			
	K183024 – Implacil Implant System	**K170398** – S.I.N. Dental Implant System	**K133510** – Neodent Implant System	**K180282 -** MIS Internal Hex Dental Implant System	**K090452** - Neoss Implant System 03,25	**K140440** - Noris Medical, Ltd.
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	Neoss Limited	Noris Medical, Ltd.
Implant-to-abutment connection	HE interface HI interface	HE interface HI interface	HE interface	HI interface	HI interface	HI interface
Diameter (mm)	HE: 3.3, 4.0, 5.0 HI: 3.3, 4.0, 5.0	HE: 3.6, 4.1, 5.0 HI: 3.8, 4.5	HE: 3.3, 4.1, 4.3, 5.0	HI: 3.75, 4.0, 5.5, 6.0, 6.5	HI: 3.25	HI: 3.8, 4.0, 5.4
Gingival height (mm)	HE: 1, 2, 3, 4, 5 HI: 1, 2, 3, 4, 5	HE: 1, 2, 3, 4 HI: 1, 2, 3, 4	HE:1, 2, 3	HI: 1, 2, 3	HI: 1	HI: 1, 2, 3, 4
Post Height (mm)	9, 10	5, 5.5	4, 6	4, 6	8	9.5, 10.5, 11.5, 12.5
Anti-rotational feature	Yes	No	No	No	Yes	No
Raw material	CPTi	Ti alloy	Ti alloy	Ti alloy	CPTi	Ti alloy
Surface	Machined	Machined/ Anodized	Machined	Machined/Anodized	Machined	Machined
Angulation	0, 15, 25°	0°	0, 17, 30°	0, 10, 15, 20, 25°	0, 20°	0, 15, 25°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided sterile for irradiation.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by irradiation	Provided non-sterile, to be steam sterilized prior use.

Table 5.11: SE comparison on Smart and Ideale abutment

Trade Name Information	**SUBJECT DEVICES**	**REFERENCE DEVICES**
	K183024 – Implacil Implant System	**K101945** – Neodent Implant System
	Implacil de Bortoli Material Odontologico Ltda	JJGC Industria e Comercio de Materiais Dentarios S.A.
Implant-to-abutment connection	Conical interface	Conical interface
Diameter (mm)	3.3, 4.5	3.3, 4.5
Gingival height (mm)	0.8, 1.5, 2.5, 3.5, 4.5, 5.5	0.8, 1.5, 2.5, 3.5, 4.5, 5.5
Cementable Height	4, 6	4, 6
Anti -rotational feature	Yes	Yes
Raw material	CPTi Ti alloy	Ti alloy
Surface	Machined/Anodized	Machined
Angulation	0°, 17°, 30°	0°, 17°, 30°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by ethylene oxide.

Table 5.12: SE comparison on O'ring Abutment

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE			
	K183024 – Implacil Implant System	**K170398** - S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K180282 -** MIS Internal Hex Dental Implant System	**K101945** – Neodent Implant System	**K173819 –** MyPlant II Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	JJGC Industria e Comercio de Materiais Dentarios S.A.	Hager & Meisinger GmbH
Implant-to-abutment connection	HE interface HI interface Conical interface (CM AR)	HE interface HI interface	HE interface	HI interface	Conical interface (CM)	Conical interface (CM)
Diameter (mm)	HE: 3.5, 4.0, 5.0 HI: 3.5, 4.0, 5.0 CM AR: 4.0	HE: 3.4, 4.1, 5.0 HI: 3.8, 4.5	HE: 4.1, 4.3, 5.0	HI: 4.0, 5.0	CM: 3.5	Snap Attachment Sphere: 2.25
Height (mm)	HE: 1, 2, 3, 4, 5 HI: 1, 2, 3, 4, 5 CM AR: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5	HE: 2, 3 HI: 2, 3	HE: 2, 3, 4, 5	HI: 1, 2, 3, 4, 5	CM: 1.5, 2.5, 3.5, 4.5, 5.5	CM: 1.5, 3.0, 4.5
Anti-rotational feature	No	No	No	No	No	No
Raw material	CPTi	Ti alloy	Ti alloy	Ti alloy	Ti alloy	CPTi
Surface	Machined	Machined	Machined	Machined Machined/TiN	Machined	Machined
Angulation	0°	0°	0°	0, 15, 25°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Unknown	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.

Table 5.13: SE comparison on UCLA abutments

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
	K183024 – Implacil Implant System	**K170398** – S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K180282 –** MIS Internal Hex Dental Implant System	**K173902 -** – Neodent Implant System – GM Line
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	MIS Implants Technologies Ltd.	JJGC Industria e Comercio de Materiais Dentarios S.A.
Implant-to-abutment connection	HE interface HI interface Conical interface	HE interface HI interface	HE interface	HI interface	Conical interface
Diameter (mm)	3.5, 4.0, 5.0	3.6, 4.1	4.1, 4.3, 5.0	3.75, 5.0	3.5/3.75, 4.0/4.3, 5.0/6.0
Gingival Height (mm)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Anti-rotational feature	Yes	Yes	Yes	Yes	Yes
Raw material	CPTi CoCr/POM	Ti alloy CoCr/POM	Ti alloy Noble/POM Zirconia	Gold/POM	CoCr/POM
Surface	Machined	Machined	Machined	Machined	Machined
Angulation	0°	0°	0°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Unknown	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.

Table 5.14: SE comparison on Copings

Trade Name Information	**SUBJECT DEVICES**	**PRIMARY PREDICATE DEVICE**	**REFERENCE DEVICE**		
	K183024 – Implacil Implant System	**K170398** – S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K101945** – Neodent Implant System	**K170608** – UF(II) Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	DIO Corporation
Implant-to-abutment connection	Not applicable (is mounted on the abutment)	Not applicable (is mounted on the abutment)	Not applicable (is mounted on the abutments)	Not applicable (is mounted on the abutments)	Not applicable (is mounted on the abutments)
Diameter (mm)	3.3, 3.5, 4.0, 4.5, 4.8, 5.0	3.8, 4.5	4.1, 5.0	3.3, 4.1, 4.5	4.95, 5.8, 6.4, 6.9
Gingival Height (mm)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Cementable height (mm)	4, 6	Unknown	Unknown	4, 6	Unknown
Anti-rotational feature	Yes	Yes	Yes	Yes	No
Raw material	CPTi CoCr/POM	Ti alloy CoCr/POM	Ti alloy Noble/POM Zirconia	Ti alloy Noble/POM POM	CPTi
Surface	Machined	Machined	Machined	Machined	Machined
Angulation	0°	0°	0°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Not informed	Provided sterile by ethylene oxide.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.

Table 5.15: SE comparison on Screws

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K183024 – Implacil Implant System	**K170398** – S.I.N. Dental Implant System	**K101207** – Neodent Implant System	**K101945** – Neodent Implant System
	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.	JJGC Industria e Comercio de Materiais Dentarios S.A.
Implant-to-abutment connection	HE interface HI interface Conical interface	HE interface HI interface	HE interface	Conical interface
Implant/Abutment diameter (mm)	3.5, 4.0	Unknown	3.3, 4.1, 4.3, 5.0	4.1, 5.0
Implant/Abutment gingival height (mm)	2, 3	Unknown	1, 2, ,3	Unknown
Cementable height (mm)	Not applicable	Not applicable	Not applicable	Not applicable
Anti-rotational feature	Not applicable	Not applicable	Not applicable	Not applicable
Raw material	Ti alloy	Ti alloy	Ti alloy	Ti alloy
Surface	Machined	Machined Machined/ Anodized	Machined	Machined
Angulation	0°	0°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Unknown	Provided sterile by ethylene oxide.	Provided sterile by ethylene oxide.

The indication for use of subject and primary predicate device K170398 are identical except for two slight changes.

1) Inclusion of "and/" in order that the indication for use statement is applicable to all the subject devices instructions for use and not misleading in any way. Currently, the subject devices are divided in 16 instructions for use. For example, many of the subject abutment are indicated for both, single-unit and also multi-unit restorations. Therefore, the proposed inclusion brings clarity to the cases where both indications are recommended and is also applicable for cases where just one of them is indicated.

2) The current submission do not have subject implants with length below 7 mm, therefore, the last sentence of the primary predicate instructions for use is not applicable.

The indication for use of subject device is within the scope of the reference devices indications for use.

The subject HE Implants are substantially equivalent to the primary predicate device K170398, and reference devices K101207, K062931 and K163634, in designs and range of dimensions. The subject HI Implants are substantially equivalent to the primary predicate device K170398, and reference devices K062931 and K180282, in designs and range of dimensions. The subject CM AR Implants are substantially equivalent to the reference devices K101945, K170608 and K163060, in designs and range of dimensions.

The subject Covers are substantially equivalent to the reference devices K101207, K180282, K101945 and K170608, in designs and range of dimensions. The subject Healing Abutments are substantially equivalent to the primary predicate K170398 and to the reference devices K101207, K180282 and K101945, in designs and range of dimensions. The subject Healing Abutment Covers are substantially equivalent to the primary predicate K170398 and to the reference devices K180282 and K170392, in designs and range of dimensions.

The subject Tapered Aesthetic Abutments are substantially equivalent to the reference devices K101207, K133510, K062931, K072642, K180282, K101945 and K170608, in designs and range of dimensions. The subject Mini Tapered and Mini Tapered Fit Abutments are substantially equivalent to the reference devices K101207, K180282, K072642, K101945 and K170608, in designs and range of dimensions. The subject Abutments are substantially equivalent to the primary predicate device K170398, and reference devices K133510, K180282, K090452 and K140440, in designs and range of dimensions. The subject Smart and Ideale Abutments are substantially equivalent to the reference device K101945, in designs and range of dimensions.

The subject O'ring Abutment is substantially equivalent to the primary predicate device K170398, and reference devices K101207, K180282, K101945 and K173819, in designs and range of dimensions. The reference device K101207 is for the HE connection in the heights not encompassed by the primary predicate device.

The subject UCLA abutment are substantially equivalent to the primary predicate device K170398, and reference devices K101207, K180282 and K173902 in raw material, designs and range of dimensions. The subject Copings are substantially equivalent to the primary predicate device K170398, and reference devices K101207, K101945 and K170608 in raw material, designs and range of dimensions.

The subject Screws are substantially equivalent to the primary predicate device K170398, and reference devices K101207 and K101945 in raw material, designs and range of dimensions.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

Sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, ISO 17665-2. Sterile barrier shelf life testing (accelerated aging according to ASTM F1980); package integrity according to ASTM F1929 and ASTM F88/F88M; sterility of the package content according to ISO 11737-2. The biocompatibility of the subject devices materials was supported by cytotoxicity testing according to ISO 10993-5 and ISO 10993-12. Pyrogenicity monitoring according to AAMI/ANSI ST72. Mechanical performance demonstrated through dynamic fatigue testing according to ISO 14801 and static torsional loading test according ISO/TS 13498:2011. No clinical data were included in this submission.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified primary predicate and reference devices.