February 11, 2021

D.S.P Industrial Eireli
% Graziela Brum
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrarivos Ltda
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096-570
BRAZIL

Re: K192839
Trade/Device Name: DSP Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 8, 2021
Received: January 12, 2021

Dear Graziela Brum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K192839

Device Name
DSP Implant System

Indications for Use *(Describe)*
The DSP Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	D.S.P. Industrial Eireli Rua Marechal Floriano Peixoto 303 -Ouro Verde II Campo Largo, Paraná, Brazil 83606-290 Telephone +55 (41) 3291-2200
Prepared by	Janine Treter and Graziela Brum Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda Email:graziela@rapassarini.com.br Telephone +55 (16) 3421-8488
Date prepared	10/Feb/2021

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary Predicate Device	**K101207** - Neodent Implant System -JJGC Industria e Comercio de Materiais Dentarios S.A
Reference Devices	**K023113** - Replace TiUnite Endosseous Implant - Nobel Biocare USA Inc **K083561**- Neoss ProActive Implant - Neoss Limited **K925762** - Branemark System Self-Tapping Fixture - Nobelpharma USA, Inc **K101945**- Neodent Implant System - JJGC Industria e Comercio de Materiais Dentarios S.A. **K150669** - Neoss TiBase and CoCr Abutments-Neoss Ltd. **K163634** - - External Hex Implants - Southern Implants (Pty) Ltd. **K170398** - S.I.N. Dental Implant System - S.I.N. Sistema de Implante Nacional S.A **K183024** – Implacil Implant System -Implacil de Bortoli Material Odontologico Ltda

INDICATIONS FOR USE

The DSP 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.

SUBJECT DEVICE DESCRIPTION

DSP Implant System is composed of the External Hex (HE) implant line. The implant line is composed of implants and related prosthetic components available in multiple designs.

DSP implants are made of commercially pure titanium (ASTM F67). DSP prosthetic components are made of commercially pure titanium or cobalt-molybdenum alloy (ASTM F1537). DSP implant system screws (abutment and prosthetic screws) are made of titanium alloy (ASTM F136).

The HE implant line is named after the External Hex implant-to-abutment interface. It is subdivided in External Hex SLIM (HE SLIM), External Hex BIOFIT (HE BIOFIT), External Hex SOULFIT (HE SOULFIT), External Hex PROPFIT (HE PROPFIT) and External Hex WAYFIT (HE WAYFIT). The HE implants are bone-level implants.

The subject device abutments components mate exclusively with the subject implants of the same line.

COCR BASE UCLA

The CoCr Base UCLAs are prosthetic components to be installed onto DSP HE implants to support the definitive prosthesis. The CoCr Base UCLAs are composed of two parts: the CoCr alloy part that interfaces directly to the implant and a polymer cylinder part for fabrication of a cast prosthesis by a burnout technique. The cylinder part is made of polyoxymethylene polymer (POM) and the CoCr part is made of a Cobalt-Chromium-based alloy. They are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136.

COCR UCLA

The CoCr UCLAs are prosthetic components to be installed onto DSP HE implants to support the definitive prosthesis. The CoCr UCLAs interfaces directly to the implant and the top portion is cast out of CoCr metal using the lost-wax technique. They are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136. The CoCr UCLA is a multi-unit abutment intended to be hand-milled to a patient-matched shape with a bridge or bar cast onto it.

TITANIUM ABUTMENTS

The Titanium Abutments are intermediary prosthetic components to be installed onto DSP HE implants to support the definitive prosthesis. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67. They are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136. The Titanium Abutments it is the bottom half of a two-piece abutment. The second piece of this two-piece abutment is cast out of CoCr metal using the lost-wax technique. The two pieces are

then cemented together. For the cementation, it is recommended to use dual resinous cement Panavia F (Kuraray Co Ltd Tokyo-Japan).

COCR BASE COPINGS

The CoCr Base Copings are prosthetic components to be installed over the Mini Conical Abutment to support the definitive prosthesis. The CoCr Base Coping are composed of two parts: the CoCr alloy part that interfaces to the abutment and a polymer cylinder part for fabrication of a cast prosthesis by a burnout technique. The cylinder part is made of polyoxymethylene polymer (POM) and the CoCr part is made of a Cobalt-Chromium-based alloy. They are supplied with a removable prosthetic screw made of titanium alloy in accordance with standard ASTM F136.

MINI CONICAL ABUTMENTS

The Mini Conical Abutments are intermediary prosthetic components to be installed onto DSP implants (HE) to support the final prosthesis. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67 and are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136. The prosthesis is to be screw-retained over the Mini Conical Abutment.

Mini Conical Abutments are indicated multi-unit restorations only. They are to be used exclusively with a coping extending the abutment portion to a minimum of 4.9 mm.

ONE STEP HYBRID TECHNIQUE

The One Step Hybrid Titanium Coping is a definitive prosthetic component intended for the One Step Hybrid Technique. It is made of commercially pure titanium (Grade 4) conforming to ASTM F67 and are supplied with a removable prosthetic screw made of titanium alloy in accordance with standard ASTM F136. The One Step Hybrid Titanium Coping is compatible with the HE Mini Conical Abutment. The prosthesis is to be cement-retained over the One Step Hybrid Titanium Coping.

COVER

The Cover is a device intended for temporary use, made of commercially pure titanium (Grade 4) conforming to ASTM F67. In one end have fitting for a manual screwdriver that allows its installation and in the other, presents the interface for HE implants line coupling.

HEALING ABUTMENT

The Healing Abutments are straight devices intended for temporary use, made of commercially pure titanium (Grade 4) conforming to ASTM F67. They are available in standard or anatomical shapes to be installed over the implant. In one end have fitting for its manual installation driver and in the other, present the interface compatible with the implant line (HE).

PROTECTION CYLINDER

The Protection Cylinders are prosthetic components intended for temporary use, made of commercially pure titanium (Grade 4) conforming to ASTM F67. They are available in a cap shape to be installed over the Conventional Abutment (Mini Conical Abutment). In one of the ends it has a fit for the manual driver that

allows its installation and in the other end the compatible geometry for installation over the abutment. It has a coupled screw for attachment on the corresponding abutment.

TEMPORARY ABUTMENT

The Temporary Abutments are temporary prosthetic components to be installed onto DSP HE implants) to support provisional prosthesis. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67 and are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136. The prosthesis is to be cement-retained over the Temporary Abutment.

ANATOMICAL ABUTMENTS

The Anatomical Abutments are intermediary prosthetic components to be installed onto DSP implants (HE) to support the final prosthesis. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67. They are supplied with a removable abutment screw made of titanium alloy in accordance with standard ASTM F136. The prosthesis is to be cement-retained over the Anatomical Abutments.

O'RING ABUTMENT

The O'ring abutments are straight ball-type intermediary prosthetic components to be installed onto DSP HE implants to support the final prosthesis. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67.

The O'ring is indicated for the attachment of full or partial overdentures for multi-unit restorations.

TEMPORARY COPINGS

The Temporary Copings are temporary coping-type prosthetic components to be installed over a Conventional Abutment (HE), specifically, the Temporary Copings are screw-retained on the Mini Conical Abutments. They are made of commercially pure titanium (Grade 4) conforming to ASTM F67 and are supplied with a removable prosthetic screw made of titanium alloy in accordance with standard ASTM F136. The prosthesis is to be cement over the Temporary Copings.

ABUTMENT SCREW

The Abutment Screws (Temporary Abutment, UCLA-type Abutment or Conventional Abutment) are manufactured in titanium alloy in accordance with ASTM F136 - Ti6Al4V-ELI. They are composed of two different parts: head and body. The head has a geometry for the fitting of the Driver/Connection which enable its use; and the body has a thread with a geometry which allow its fixation.

PROSTHETIC SCREWS

The Prosthetic Screws are manufactured in titanium alloy in accordance with ASTM F136 - Ti6Al4V-ELI. They are intended to connect the prosthesis in the Conventional Abutments, specifically, the Mini Conical Abutments. The Prosthetic Screws are composed of two different parts: head and body. The head has a geometry for the fitting of the Driver/Connection which enable its use; and the body has a thread with a geometry which allow its fixation.

TECHNOLOGICAL CHARACTERISTICS

The subject devices indications for use statement is equivalent to the primary predicate device K101207. The phrase “multiple tooth application may be rigidly splinted” was suppressed since it is up it is up to the professional in charge to select proper technique for multi-unit restoration. The indication for use of the subject device is within the scope of the reference devices. Refer to table 5.1.

Differences in the design features between the subject devices and primary predicate devices K101207 are addressed by comparison to the reference devices in the tables 5.2 to 5.17 below.

Table 5.1: SE comparison on Indication for Use Statements

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT
SUBJECT DEVICE	**K192839** - DSP Implant System D.S.P. Industrial Eireli	The DSP 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.
PRIMARY PREDICATE DEVICE	**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.
REFERENCE DEVICES	**K023113** - Replace TiUnite Endosseous Implant Nobel Biocare USA Inc	The Nobel Biocare Replace TiUnite Endosseous Implant is intended to be placed in theupper or lower jaw to support prosthetic devices such as artificial teeth, and to restore patient's chewing function, This may be accomplished using a two stage surgical procedure or a single stage surgical procedure. If the single stage surgical procedure is used, these implants may be loaded immediately following insertion - provided - at least four implants are placed and splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foraminae) where good initial stability of the implants with or without bi-cortical anchorage, can most often be obtained.
	K083561- Neoss ProActive Implant Neoss Limited	The Neoss ProActive Implant is for single-stage and two-stage surgical procedures and cement or screw retained restorations. The Neoss ProActive Implant are intended for immediate placement and function 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.
	K925762 - Branemark System Self-Tapping Fixture Nobelpharma USA, Inc	The Nobelpharma Branemark System® - Self-Tapping Fixture is intended to be used in edentulous and partially edentulous patients to restore chewing functions of those patients.
	K101945- Neodent Implant System	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support fqr prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or

K192839 - DSP Implant System

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT
	JJGC Industria e Comercio de Materiais Dentarios S.A.	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.
	K150669 - Neoss TiBase and CoCr Abutments Neoss Ltd.	Neoss TiBase: Neoss Abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation. The Neoss TiBase is compatible with the Sirona Dental System inCoris ZI Meso L. All digitally designed copings and/or crowns for use with the Neoss TiBase Abutments are to be designed and milled using the Sirona Dental CAD/CAM System. Neoss CoCr Abutments: Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
	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. Implants with lengths less than 7 mm are intended for delayed loading only.
	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.
	K183024 – Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support forsingle-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.

Table 5.2: SE comparison on HE SLIM implants

Trade Name Information	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES	
	K192839 - DSP Implant System	**K101207** – Neodent Implant System	**K023113 -** Replace TiUnite Endosseous Implant	**K170398** - S.I.N. Dental Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.	Nobel Biocare USA Inc	S.I.N. Sistema de Implante Nacional S.A.
HE SLIM				
Implant-to-abutment connection	HE	HE	Internal tri-channel	HE
Root-type design	Cylindrical	Cylindrical Tapered	Tapered	Cylindrical
Prosthesis attachment	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant diameter: Length (mm)	Cylindrical **3.3:** 8.5, 10, 11.5, 13, 15, 17	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	 Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16 **6.0**: 10, 13, 16	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
Raw Material	CPTi Gr4	CPTi Gr4	CPTi Gr4 (cold worked titanium)	CPTi Gr4
Surface	Treated. Grit-blasted and acid-etched. Machined collar: h 1.0 mm	Treated. Grit-blasted and acid-etched. Treated collar : h *unknown*	Treated, TiUnite Machined collar: h 1.5 mm	Treated. Acid-etched and HA Machined collar: h 0.7 mm
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.3: SE comparison on HE BIOFIT implants

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICES		
	K192839 - DSP Implant System	**K083561-** Neoss ProActive Implant	**K023113 -** Replace TiUnite Endosseous Implant	**K170398** - S.I.N. Dental Implant System
	D.S.P. Industrial Eireli	Neoss Limited	Nobel Biocare USA Inc	S.I.N. Sistema de Implante Nacional S.A.
HE BIOFIT				
Implant-to-abutment connection	HE	Internal Hex (NeoLoc)	Internal tri-channel	HE
Root-type design	Cylindrical	Cylindrical	Tapered	Cylindrical
Prosthesis attachment	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant diameter: Length (mm)	Cylindrical **3.5**: 8.1, 9.6, 11.1, 12.6, 14.6, 16.6 **3.75**: 7, 8.1, 9.6, 11.1, 12.6, 14.6, 16.6 **4.0**:, 7, 8.1, 9.6, 11.1, 12.6, 14.6 **4.5**: 7, 8.1, 9.6, 11.1, 12.6, 14.6, 16.6 **5.0**: 7, 8.1, 9.6, 11.1, 12.6	Cylindrical: **3.5:** 7, 9, 11, 13, 15, 17 **4.0:** 7, 9, 11, 13, 15, 17 **4.5:** 7, 9, 11, 13, 15, 17 **5.0:** 7, 9, 11, 13, 15 **5.5:** 7, 9, 11, 13	Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16 **6.0**: 10, 13, 16	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
Raw Material	CPTi Gr4	Not informed	CPTi Gr4 (cold worked titanium)	CPTi Gr4
Surface	Treated. Grit-blasted and acid-etched Machined collar: h 0.3 mm	Treated. Grit-blasted and acid-etched Treated collar: h unknown	Treated, TiUnite Machined collar: h 1.5 mm	Acid-etched and HA Machined collar: h 0.7 mm
Sterilization	Provided sterile by irradiation	Provided sterile. Method not informed.	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.4: SE comparison on HE SOULFIT implants

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICES		
	K192839 - DSP Implant System	**K023113 -** Replace TiUnite Endosseous Implant	**K925762 -** Branemark System Self-Tapping Fixture	**K170398** - S.I.N. Dental Implant System
	D.S.P. Industrial Eireli	Nobel Biocare USA Inc	Nobelpharma USA, Inc	S.I.N. Sistema de Implante Nacional S.A.
HE SOULFIT				
Implant-to-abutment connection	HE	Internal tri-channel	HE	HE
Root-type design	Cylindrical	Tapered	Cylindrical	Cylindrical
Prosthesis attachment	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant diameter: Length	Cylindrical **3.5**: 8.5, 10, 11.5, 13, 15 **3.75**: 7, 8.5, 10, 11.5, 13, 15, 17 **4.0**: 7, 8.5, 10, 11.5, 13, 15, 17 **5.0**: 7, 8.5, 10, 11.5, 13	Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16 **6.0**: 10, 13, 16	Cylindrical: **3.3:** 10, 11.5, 13, 15 **3.75:** 7, 8.5, 10, 11.5, 13, 15, 18 **4.0:** 7, 8.5, 10, 11.5, 13, 15, 18 **5.0:** 7, 8.5, 10, 11.5, 13, 15, 18	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
Raw Material	CPTi Gr4	CPTi Gr4 (cold worked titanium)	CPTi Gr4	CPTi Gr4
Surface	Treated. Grit-blasted and acid-etched Machined collar: h max 0.8 mm	Treated, TiUnite Machined collar: h 1.5 mm	Treated. Grit-blasted and acid-etched. Machined collar: h 0.8 mm	Acid-etched and HA Machined collar: h 0.7 mm
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.5: SE comparison on HE WAYFIT implants

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICE	
	K192839 - DSP Implant System	**K023113 -** Replace TiUnite Endosseous Implant	**K163634 - -** External Hex Implants
	D.S.P. Industrial Eireli	Nobel Biocare USA Inc	Southern Implants (Pty) Ltd.
HE WAYFIT			
Implant-to-abutment connection	HE	Internal tri-channel	HE
Root-type design	Tapered	Tapered	Cylindrical Tapered
Prosthesis attachment	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant diameter: Length (mm)	Tapered **3.8**: 8.5, 10, 11.5, 13, 15, **4.3**: 8.5, 10, 11.5, 13, 15 **5.0**: 8.5, 10, 11.5, 13, 15	Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16 **6.0**: 10, 13, 16	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 ´ 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
Raw Material	CPTi Gr4	CPTi Gr4 (cold worked titanium)	CPTi Gr4
Surface	Treated. Grit-blasted and acid-etched Machined collar : h max 0.7 mm	Treated, TiUnite Machined collar: h 1.5 mm	Grit-blasted and acid-etched
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation

Table 5.6: SE comparison on HE PROPFIT implants

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICES	
	K192839 - DSP Implant System	**K023113 -** Replace TiUnite Endosseous Implant	**K163634 - -** External Hex Implants
	D.S.P. Industrial Eireli	Nobel Biocare USA Inc	Southern Implants (Pty) Ltd.
HE PROPFIT			
Implant-to-abutment connection	HE	Internal tri-channel	HE
Root-type design	Tapered	Tapered	Cylindrical Tapered
Prosthesis attachment	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture	Screw-retained Cement-retained Overdenture
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant diameter: Length (mm)	Tapered **3.8**: 8.5, 10, 11.5, 13, 15, **4.3**: 8.5, 10, 11.5, 13, 15 **5.0**: 8.5, 10, 11.5, 13, 15	Tapered: **3.5**: 10, 13, 16 **4.3**: 10, 13, 16 **5.0**: 10, 13, 16 **6.0**: 10, 13, 16	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
Raw Material	CPTi Gr4	CPTi Gr4 (cold worked titanium)	CPTi Gr4
Surface	Treated. Grit-blasted and acid-etched Machined collar: h 1.0 mm.	Treated, TiUnite Machined collar: h 1.5 mm	Grit-blasted and acid-etched
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	

Table 5.7: SE comparison on Covers, Healing Abutments and Protection Cylinders

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.
COVER, HEALING ABUTMENT, PROTECTION CYLINDER		
Implant-to-abutment connection	HE	HE
Diameter (mm)	3.3, 4.1, 4.8	3.3, 4.1, 4.3, 5.0
Gingival Height (mm)	2, 3, 4, 5, 6	2, 3, 4, 5, 6
Raw material	CPTi Gr4	Ti alloy
Surface	Machined	Machined
Angulation	0°	0°
Load	No occlusal load	No occlusal load
Sterility	Provided sterile by irradiation.	Provided sterile by ethylene oxide.

Table 5.8: SE comparison on Temporary Abutment

Trade Name Information	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.
TEMPORARY ABUTMENT		
Compatibility	HE	HE
Application	Provisional prosthesis over the implant	Provisional prosthesis over the implant
Temporary timeframe	Up to 180 days	Up to 180 days
Diameter (mm)	3.3, 4.1	3.3, 4.1, 4.3, 5.0
Gingival height (mm)	1, 2, 3	1, 2, 3, 4
Prosthesis retention	Cement-retained	Cement-retained
Raw material	CPTi Gr 4	Ti alloy
Surface	Machined	Machined
Angulation	0°	0°
Sterility	Provided sterile for irradiation	Provided sterile by ethylene oxide.

Table 5.9: SE comparison on CoCr Base UCLA

Trade Name Information	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.
COCR BASE UCLA		
Compatibility	HE	HE
Application	Definitive prosthesis over the implant	Definitive prosthesis over the implant
Diameter (mm)	3.3, 4.1	4.1, 5.0
Prosthesis retention	Casted retained	Casted retained
Raw material	CoCr/ POM	CoCr/ POM
Surface	Machined/ Cast	Machined/ Cast
Angulation	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.

Table 5.10: SE comparison on CoCr UCLA

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICES	
	K192839 - DSP Implant System	**K150669 -** Neoss TiBase and CoCr Abutments	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	Neoss Ltd.	Implacil de Bortoli Material Odontologico Ltda
COCR UCLA			
Compatibility	HE	Internal Hex (NeoLoc)	HE, Internal Hex, Conical
Application	Definitive prosthesis over the implant	Definitive prosthesis over the implant	Definitive prosthesis over the implant
Diameter (mm)	3.3, 4.1	4.5	3.5, 4.0, 5.0
Gingival height (mm)	1.0	0.7	Unknown
Prosthesis retention	Casted retained	Casted retained	Casted retained
Raw material	CoCr	CoCr	CoCr/ POM
Surface	Machined/Cast	Machined/Cast	Machined/ Cast
Angulation	0°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.

Table 5.11: SE comparison on Anatomical Abutments

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICE
	K192839 - DSP Implant System	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	Implacil de Bortoli Material Odontologico Ltda
ANATOMICAL ABUTMENTS		
Implant-to-abutment connection	HE	HE, Internal Hex, Conical
Diameter (mm)	3.3, 3.6, 4.0, 4.1	3.3, 3.5, 4.0, 4.5, 5.0
Gingival height (mm)	1, 2, 3	0.8, 1, 1.5, 2, 2.5, 3, 3.5, 4.5, 5.5
Prosthesis retention	Cement-retained	Cement-retained
Prosthetic height (mm)	6	4,6
Raw material	CPTi Gr 4	CPTi Gr 4
Surface	Machined	Machined Machined/Anodized
Angulation	0°	0, 15, 17, 25, 30°
Sterility	Provided sterile for irradiation.	Provided non-sterile, to be steam sterilized prior use.

Table 5.12: SE comparison on Titanium Abutments

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.
TITANIUM ABUTMENTS		
Implant-to-abutment connection	HE	HE
Diameter (mm)	3.3, 3.6, 4.1	4.1, 5.0
Gingival height (mm)	1, 2, 3	Not applicable
Prosthesis retention	Cement-retained	Casted retained
Prosthetic height (mm)	4.7, 6.0	Unkown
Raw material	CPTi Gr 4/ CoCr Alloy	CoCr/ CoCr Alloy
Surface	Machined/Cast	Machined/ Cast
Angulation	0°	0°
Sterility	Provided sterile for irradiation.	Provided non-sterile, to be steam sterilized prior use

Table 5.13: SE comparison on Mini Conical Abutments

Trade Name Information	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.	Implacil de Bortoli Material Odontologico Ltda
MINI CONICAL ABUTMENTS			
Implant-to-abutment connection	HE	HE	HE, Internal Hex, Conical
Diameter (mm)	3.3, 4.1	3.3, 4.1, 4.3, 5.0	3.5, 4.0, 4.8, 5.0
Gingival height (mm)	1, 2, 3, 4, 5.5	1, 2, 3, 4	0.8, 1, 1.5, 2, 2.5, 3, 3.5, 4.5, 5.5
Prosthesis retention	Screw-retained	Screw-retained	Screw-retained
Raw material	CPTi Gr 4	Titanium alloy	CPTi Gr 4
Surface	Machined	Machined	Machined
Angulation	0°	0, 17, 30°	0, 17, 30°
Sterility	Provided sterile for irradiation.	Provided sterile by ethylene oxide.	Provided non-sterile, to be steam sterilized prior use.

Table 5.14: SE comparison on O'ring Abutment

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE
	K192839 - DSP Implant System	**K101207** – Neodent Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.
O'RING ABUTMENT		
Compatibility	HE	HE
Diameter (mm)	3.3, 4.1	4.1, 4.3, 5.0
Gingival height (mm)	1, 2, 3, 4, 5	2, 3, 4, 5
Raw material	CPTi Gr 4	CPTi Gr 4
Surface	Machined	Machined/TiN
Angulation	0°	0°
Sterility	Provided sterile for irradiation.	Provided sterile by ethylene oxide.

Table 5.15: SE comparison on Temporary Coping

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICE
	K192839 - DSP Implant System	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	Implacil de Bortoli Material Odontologico Ltda
TEMPORARY COPING		
Compatibility	HE	HE, HI
Application	Provisional prosthesis over the abutment	Provisional prosthesis over the abutment
Diameter (mm)	4.8	4.8
Prosthesis retention	Cement-retained	Cement-retained
Raw material	CPTi Gr 4	CPTi Gr 4
Surface	Machined	Machined
Angulation	0°	0°
Sterility	Provided sterile for irradiation.	Provided non-sterile, to be steam sterilized prior use.

Table 5.16: SE comparison on CoCr Base Coping

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICE
	K192839 - DSP Implant System	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	Implacil de Bortoli Material Odontologico Ltda
COCR BASE COPING		
Compatibility	HE	HE, HI
Application	Definitive prosthesis over the abutment	Definitive prosthesis over the abutment
Diameter (mm)	4.8	3.5, 4.0, 5.0
Prosthesis retention	Cement-retained	Cement-retained
Raw material	CoCr/ POM	CoCr/ POM
Surface	Machined/Cast	Machined/Cast
Angulation	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.

Table 5.17: SE comparison on One Step Hybrid Coping

Trade Name Information	SUBJECT DEVICE	REFERENCE DEVICE	
	K192839 - DSP Implant System	**K101945**- Neodent Implant System	**K183024** – Implacil Implant System
	D.S.P. Industrial Eireli	JJGC Industria e Comercio de Materiais Dentarios S.A.	Implacil de Bortoli Material Odontologico Ltda
ONE STEP HYBRID COPING			
Compatibility	HE	Conical Connection	HE, HI
Application	Definitive prosthesis over the abutment	Definitive prosthesis over the abutment	Definitive prosthesis over the abutment
Diameter (mm)	4.0, 4.2, 4.8	4.1, 5.0	3.5, 4.0, 5.0
Prosthesis retention	Cement-retained	Cement-retained	Cement-retained
Raw material	CPTi Gr 4	CPTi Gr 4	CoCr/ POM
Surface	Machined	Machined	Machined
Angulation	0°	0°	0°
Sterility	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.	Provided non-sterile, to be steam sterilized prior use.

The subject HE SLIM implants are substantially equivalent to the primary predicate device K101207 and reference devices K023113 and K170398. The primary predicate device K101207 is for substantial equivalence of the length 17 mm while other dimensions are covered by K170398. Both K101207 and K170398 are also for body geometrical features. The K023113 is for substantial equivalence of the height of the machined collar.

Considering all the subject implants, the machined collar is implantable as the reference device K023113.

The subject HE BIOFIT implants are substantially equivalent to the reference devices K083561, K023113 and K170398. The K083561 is for substantial equivalence of the length 16,6 mm for diameters 3.5 mm. The remain dimensions are covered by K170398. Both K083561 and K170398 are also for body geometrical features. The K023113 is for substantial equivalence of the height of the machined collar.

The subject HE SOULFIT implants are substantially equivalent to the reference devices K023113, K925762 and K170398. K170398 is for body geometrical features and range of dimensions while K023113 is for substantial equivalence of the height of the machined collar. The K925762 is for substantial equivalence of the dimensions not encompassed by K170398 which are the length 17 mm for diameters 3.75 and 4.0 mm. The K023113 is for substantial equivalence of the height of the machined collar.

The subject HE WAYFIT and PROPFIT implants are substantially equivalent to the reference devices K123022 and K163634. The K163634 is for substantial equivalence of the range of dimensions (diameter and length). The K023113 is for substantial equivalence of the height of the machined collar.

The subject HE PROPFIT implants are substantially equivalent to the reference devices K023113, K062931 and K163634. The K163634 is for substantial equivalence of the range of dimensions (diameter and length). The K023113 is for substantial equivalence of the height of the machined collar.

The subject Covers, Healing Abutments, Protection Cylinders, Temporary Abutments and CoCr Base UCLA are substantially equivalent to the primary predicate device K101207 in design and range of dimensions.

The subject CoCr UCLAs are substantially equivalent to the reference devices K150669 and K183024. K150669 is for substantial equivalence of the abutment entirely made of CoCr alloy while K183024 is for the range of dimensions.

The subject Anatomical Abutments are substantially equivalent to the reference device K183024 in designs and range of dimensions.

The subject Titanium Abutments are substantially equivalent are substantially equivalent to the primary predicate device K101207 in technology.

The subject Mini Conical Abutments are substantially equivalent to the primary predicate device K101207, and reference devices K183024 in designs and range of dimensions. The reference devices K183024 is for substantial equivalence of raw material.

The subject O'ring Abutment is substantially equivalent to the primary predicate device K101207 in designs and range of dimensions.

The subject Temporary Coping is substantially equivalent to the reference device K183024 in design and range of dimensions.

The subject CoCr Base Coping is substantially equivalent to the reference device K183024. The CoCr Base Coping is provided with a prosthetic screw made of titanium alloy as it is the reference device.

The subject One Step Hybrid Coping is substantially equivalent to the reference devices K101945 and K183024. The K101945 is for the design characteristics and technology and K183024 is for the implant to abutment interface.

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 testing according to ISO 10993-5. Pyrogenicity monitoring according to AAMI/ANSI ST72, The method selected to determine pyrogen limit specifications is the Bacterial Endotoxin Test (BET) performed according to USP <85> using the photometric technique. Representative samples are selected for testing based upon the raw material, manufacturing processes, and sterilization process. No clinical data were included in this submission.

In order to analyze the blasted and acid etched surface and verify if some residual contaminants substances used during implant surface treatment remains over the implant, a scanning electron microscopy (SEM) coupled with Energy Dispersive Spectroscopy (EDS) was performed. The implant surface (modified surface) was analyzed. The elements were quantified by EDS no presence of contaminating metal particles was observed.

The following FDA guidance's were followed:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 21, 2016.
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued June 16. 2016.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued March 17, 2015.
- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

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 predicate devices.