May 26, 2021

Implacil de Bortoli Material Odontologico Ltda
Thiago Toni
Quality Manager
Rua Vicente de Carvalho 178-182
Sao Paulo, Sao Paulo 01521020
BRAZIL

Re: K202832
Trade/Device Name: Implacil Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 19, 2021
Received: April 29, 2021

Dear Thiago Toni:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K202832

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	Implacil de Bortoli Material Odontologico Ltda Rua Vicente de Carvalho 178-182 São Paulo, São Paulo, Brazil 01521020 Telephone: +55 (11) 3342-5100
Contact Person	Thiago Toni Quality Manager thiago@implacil.com.br
Date Prepared	25/May/2021

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary Predicate Device	**K183024** – Implacil Implant System – Implacil de Bortoli Material Odontologico Ltda
Reference Devices	**K170392** - S.I.N. Dental Implant System - S.I.N. Sistema de Implante Nacional S.A. **K192839** - DSP Implant System - D.S.P. Industrial Eireli

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

The Maestro line of Implacil Implant System is composed of three implant-to-abutment connections which are External Hex (HE), Internal Hex (HI) and Morse Taper AR Due Cone (CM AR). All of them are bone-level implants.

The implants subject of this submission are threaded, self-tapping, root form endosseous dental implants used to support single or multiple restorations in immediate or conventional loading protocols. The subject devices are recommended for all bone density types, depending on the drill sequence used.

The implants are made of commercially pure titanium (Grade 4) conforming to ASTM F67 and are surface treated to create a rough surface using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface. The Maestro implant line has radial channels (55 °) or chambers on their external surface.

HE implants are available in tapered (conical) root-forms designs in three diameters and platforms (3.5, 4.0 and 5.0 mm). For implants diameter 3.5, there are eight available lengths (8, 9, 10, 11, 12, 13, 14, 15), while for diameters 4.0 and 5.0 there are nine lengths (7, 8, 9, 10, 11, 12, 13, 14, 15).

HI implants are available in tapered (conical) root-forms designs in three diameters and platforms (3.5, 4.0 and 5.0 mm). For implants diameter 3.5, there are eight available lengths (8, 9, 10, 11, 12, 13, 14, 15), while for diameters 4.0 and 5.0 there are nine lengths (7, 8, 9, 10, 11, 12, 13, 14, 15).

CM AR implants are available in tapered (conical) root-form design, in four diameters (3.5, 4.0, 4.5 and 5.0 mm). For implants diameter 3.5, there are eight available lengths (8, 9, 10, 11, 12, 13, 14, 15), while for diameters 4.0, 4.5 and 5.0 there are nine lengths (7, 8, 9, 10, 11, 12, 13, 14, 15).

The compatible prosthetic components mate exclusively with the subject implants of the same implant-to-abutment interface (HI, HE, CM AR). All the compatible prosthetic components were cleared under K183024.

TECHNOLOGICAL CHARACTERISTICS

The subject device and the predicate devices have the same intended use and similar technological characteristics as shown in the tables below. Differences in the design features between the subject devices and the primary predicate device K183024 are addressed by comparison to the reference devices in design and range of dimensions.

Table 5.1: SE comparison on Maestro HE implants

Trade Name Information	SUBJECT DEVICE **K202832 -** Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	PRIMARY PREDICATE DEVICE **K183024** – Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	REFERENCE DEVICE **K192839** - DSP Implant System D.S.P. Industrial Eireli	Substantial Equivalence Discussion
Indication 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.	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.	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.	**Identical** The indication for use statement is identical to the primary predicate device and is within the scope of the reference device.
Implant-to-abutment connection	HE interface	HE interface HI interface Conical connection (CM AR)	HE interface	**Identical** To the primary predicate and reference devices.
Raw Material	CPTi	CPTi	CPTi	**Identical** To the primary predicate and reference devices.
Surface	Grit-blasted and acid-etched Machined collar: h 1.0 mm	Grit-blasted and acid-etched Machined collar: h 1.0 mm	Grit-blasted and acid-etched. Machined collar: h 1.0 mm	**Equivalent** Identical to the primary predicate and reference devices.
Design – presence of chambers	Yes	No	**No**	**Different** The presence of chambers in the external surface is the only difference between the subject and primary predicate device design. The substantial equivalence is supported by external surface area comparison. No impact in mechanical performance is expected.

Trade Name Information	SUBJECT DEVICE **K202832 -** Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	PRIMARY PREDICATE DEVICE **K183024** – Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	REFERENCE DEVICE **K192839** - DSP Implant System D.S.P. Industrial Eireli	Substantial Equivalence Discussion
Implant diameter: lengths (mm)	**3.5:** 8, 9, 10, 11, 12, 13, 14, 15 **4.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15 **5.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15	**3.3:** 8, 10, 11.5, 13, 15 **3.5:** 7, 9, 11, 13, 15 **3.75:** 8, 10, 11.5, 13, 15 **4.0:** 7, 8, 9, 10, 11, 11.5, 13, 15 **4.75:** 8, 10, 11.5, 13, 15 **5.0:** 7, 9, 11, 13, 15	**3.3:** 8.5, 10, 11.5, 13, 15, 17 **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	**Equivalent** Within the range of dimensions of the primary predicate and reference devices.
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	**Identical** To the primary predicate and reference devices.

Table 5.2: SE comparison on Maestro HI implants

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES		Substantial Equivalence Discussion
	K202832 - Implacil Implant System	**K183024** – Implacil Implant System	**K170392**- S.I.N. Dental Implant System	**K192839** - DSP Implant System	
	Implacil de Bortoli Material Odontologico Ltda	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	D.S.P. Industrial Eireli	
Indication 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.	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.	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.	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.	**Identical** The indication for use statement is identical to the primary predicate device and is within the scope of the reference devices.
Implant-to-abutment connection	HI interface	HE interface HI interface Conical connection (CM AR)	Conical connection (CM)	HE interface	**Identical** To the primary predicate device.
Raw Material	CPTi	CPTi	CPTi	CPTi	**Identical** To the primary predicate and reference devices.
Surface	Grit-blasted and acid-etched Machined collar: h 1.0 mm	Grit-blasted and acid-etched Machined collar: h 1.0 mm	Grit-blasted and acid-etched	Grit-blasted and acid-etched Machined collar: h 1.0 mm	**Identical** To the primary predicate and reference devices for the grit-blasted and acid-etched surface and identical to the primary predicate and reference device K192839 for the machined collar height.

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES		Substantial Equivalence Discussion
	K202832 - Implacil Implant System	**K183024** – Implacil Implant System	**K170392**- S.I.N. Dental Implant System	**K192839** - DSP Implant System	
	Implacil de Bortoli Material Odontologico Ltda	Implacil de Bortoli Material Odontologico Ltda	S.I.N. Sistema de Implante Nacional S.A.	D.S.P. Industrial Eireli	
Design – presence of chambers	Yes	No	No	No	**Different** The presence of chambers in the external surface is only difference between the subject and primary predicate device design. The substantial equivalence is supported by external surface area comparison. No impact in mechanical performance is expected.
Implant diameter: lengths (mm)	**3.5:** 8, 9, 10, 11, 12, 13, 14, 15 **4.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15 **5.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15	**3.3:** 8, 9, 11, 13, 15 **3.5:** 8, 9, 11, 13, 15 **3.75:** 7, 9, 11, 13, 15 **4.0:** 8, 9, 11, 13, 15 **4.3:** 7, 9, 11, 13, 15 **4.75:** 7, 9, 11, 13, 15 **5.0:** 7, 9, 11, 13, 15	**2.9:** 10, 11.5, 13 **3.5**: 8.5**,**10, 11.5, 13, 15 **3.8:** 8.5, 10, 11.5, 13, 15 **4.0:** 5, 6, 7 **4.3:** 8.5**,**10, 11.5, 13, 15 **4.5:** 8.5, 10, 11.5, 13, 15 **5.0:** 5, 6, 7, 8.5**,**10, 11.5, 13, 15	**3.3:** 8.5, 10, 11.5, 13, 15, 17 **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	**Equivalent** Within the range of dimensions of the primary predicate and reference devices.
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	**Identical** To the primary predicate and reference devices.

Table 5.3: SE comparison on Maestro CM AR implants

Trade Name Information	SUBJECT DEVICE **K202832 -** Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	PRIMARY PREDICATE DEVICE **K183024** – Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	REFERENCE DEVICE **K170392**- S.I.N. Dental Implant System S.I.N. Sistema de Implante Nacional S.A.	Substantial Equivalence Discussion
Indication 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.	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.	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.	**Equivalent** The indication for use statement is identical to the primary predicate device and within the scope of the reference device.
Implant-to-abutment connection	Conical connection (CM AR)	HE interface HI interface Conical connection (CM AR)	Conical connection (CM)	**Identical** To the primary predicate device.
Raw Material	CPTi	CPTi	CPTi	**Identical** To the primary predicate device and reference devices.
Surface	Grit-blasted and acid-etched	Grit-blasted and acid-etched	Grit-blasted and acid-etched	**Identical** To the primary predicate device and reference device.
Design – presence of chambers	Yes	No	No	**Different** The presence of chambers in the external surface is only difference between the subject and primary predicate device design. The substantial equivalence is supported by external surface area comparison. No impact in mechanical performance is expected.

Trade Name Information	SUBJECT DEVICE **K202832 -** Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	PRIMARY PREDICATE DEVICE **K183024** – Implacil Implant System Implacil de Bortoli Material Odontologico Ltda	REFERENCE DEVICE **K170392**- S.I.N. Dental Implant System S.I.N. Sistema de Implante Nacional S.A.	Substantial Equivalence Discussion
Implant diameter: lengths (mm)	**3.5:** 8, 9, 10, 11, 12, 13, 14, 15 **4.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15 **4.5:** 7, 8, 9, 10, 11, 12, 13, 14, 15 **5.0:** 7, 8, 9, 10, 11, 12, 13, 14, 15	**3.3:** 8, 9, 11, 13, 15 **3.5:** 8, 9, 11, 13, 15 **3.75:** 7, 9, 11, 13, 15 **4.0:** 8, 9, 11, 13, 15 **4.3:** 7, 9, 11, 13, 15 **4.75:** 7, 9, 11, 13, 15 **5.0:** 7, 9, 11, 13, 15	**2.9:** 10, 11.5, 13 **3.5**: 8.5**,**10, 11.5, 13, 15 **3.8:** 8.5, 10, 11.5, 13, 15 **4.0:** 5, 6, 7 **4.3:** 8.5**,**10, 11.5, 13, 15 **4.5:** 8.5, 10, 11.5, 13, 15 **5.0:** 5, 6, 7, 8.5**,**10, 11.5, 13, 15	**Equivalent** Within the range of dimensions of the primary predicate and reference device.
Sterilization	Provided sterile by irradiation	Provided sterile by irradiation	Provided sterile by irradiation	**Identical** To the primary predicate device and reference device.

The indication for use statement is identical to the primary predicate device.

The subject HE, HI and CM AR implants are substantially equivalent to the primary predicate device K183024, and reference devices K170392 and K192839, in designs and range of dimensions.

For all the three implant lines, there is a difference in design between subject and primary predicate device which is the presence of the chambers in the external surface of the device. The chambers do not alter the external surface area of the implants that will be in contact with the bone, therefore, substantial equivalence is supported by the surface area analysis comparison. No impact in mechanical performance is expected.

PERFORMANCE DATA

The implants are made of unalloyed titanium, Grade 4, conforming to ASTM F67 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700). The type of titanium is the same to that used for fabrication of the primary predicate devices cleared under K183024. The subject devices undergo to the same manufacturing processes, including surface treatment step to the cited predicate device.

The sterilization method, sterile barrier shelf life, package integrity, and pyrogenicity monitoring for the subject device are unchanged from the K183024 submission. Mechanical performance through dynamic fatigue testing according to ISO 14801 was supported by K183024.

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.