Inosys, Inc.
Calvin Shim
Vice President
545 W 45th St.
Floor 11
New York, New York 10036

June 17, 2026

Re: K260006
Trade/Device Name: INOSS System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 24, 2025
Received: May 19, 2026

Dear Calvin Shim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260006

Please provide the device trade name(s).

INOSS System

Please provide your Indications for Use below.

INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
(K260006)

Submitter :

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Device Information :

Device Name : INOSS System

Common Name : Endosseous dental implant

Classification : II

Primary Product Code : DZE

Secondary Product Code : NHA

Regulation Number : 872.3640

Date Prepared : June 15, 2026

Predicate Device

• Predicate device
K170608, DIO Corporation, UF(II) Implant System

• Reference devices
K182194, DIO Corporation, UV Active Implant System
K212533, Institut Straumann AG, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants
K163194, JJGC Industria e Comercio de Materiais Dentarios SA, Neodent Implant System - GM Line
K210826, MegaGen Implant Co., Ltd., Healing Abutment, Cover Screw
K182081, J Dental Care S.r.l., JDentalCare® Implant System JDIcon®
K222636, Hiossen Inc., ET Abutment System
K172100, TruAbutment Inc., URIS OMNI System
K161689, OSSTEM Implant Co., Ltd., OSSTEM Implant System - Abutment

Device Description

INOSS Fixture of INOSS System is specially designed for use in dental implant surgery. A successfully osseointegrated dental implant will achieve a firm implant when the fixture is operated under controlled conditions per well-known clinical studies. There are intended for use in partially or fully edentulous mandibles and maxillae, in support of single-unit restorations. The Fixture is made of Unalloyed Titanium Grade 4 (ASTM F67) which has a SAT (Sandblasted Acid-etched Treatment) treated surface. These Fixtures can be used in one-stage surgery method or two-stage surgery method. The Fixture is a surgical component that interfaces with the bone of the jaw to support a dental prosthesis such as a crown, bridge and denture. Fixture connects with other components in order to function. The Fixture design includes two types. The difference between the two fixture types is the platform diameter. One type features a reduced platform diameter that enables platform switching.

[The dimension of INOSS Fixture]

- Ø3.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø4.3 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø4.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø5.4 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø6.2 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm

INOSS Abutments are intended for use for the recovery of the patient`s masticatory movement, and this is an upper structure of the implant to support the prosthetics such as implants. INOSS Abutments do not allow angular restorations. It consists of healing abutment, cover screw, stock abutment and abutment screw.

[The dimension of INOSS Abutments]

No.	Product Name	Dimension
1	Cover Screw	Ø3.5 : Length 5.1mm Ø4.5 : Length 5.1mm Ø5.7 : Length 5.1mm
2	Healing Abutment	Ø3.5 : Height 3mm, 5mm, 7mm Ø4.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø4.5 : Height 3mm, 5mm, 7mm Ø5.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø5.5 : Height 3mm, 5mm, 7mm Ø5.9 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø6.5 : Height 3mm, 5mm, 7mm Ø7.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm
3	Stock Abutment	Ø4.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0) Ø5.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0) Ø6.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0)
4	Abutment Screw	Ø1.95 x 8.2mm

Indications for Use

INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System 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.

Substantial Equivalence

The subject device is substantially equivalent in indications and design principles to the predicate device and the reference device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the predicate device, and the reference device.

The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging connection. Therefore, its Indications for Use are limited to “a root form means for single-units' prosthetic attachment to restore a patient's chewing function.”

In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as “a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function.”

There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System).

The differences in the indications for use between the subject and predicate devices do not substantively alter their intended use and therefore do not impact the Substantial Equivalence determination.

The prosthetic interface connection, material, surface treatment and sterilization of INOSS Fixture are substantially equivalent to that of the predicate device(K170608) except for the wording regarding the name of surface treatment such as SLA. The differences in the specific wording do not change the surface treatment.

All size range of the INOSS Fixture as subject device is substantially equivalent to that of the predicate device(K170608), reference device(K182194), reference device(K212533), and reference device(K111889). Ø3.9, Ø4.3 with all length of INOSS Fixture as subject device is substantially equivalent to that of reference device(K163194). Ø4.9, Ø5.4 with all length of INOSS Fixture as subject device is substantially equivalent to that of predicate device(K170608). Ø6.2 with length 8.0mm, 10.0mm, 11.5mm and 13.0mm of the INOSS Fixture as subject device is substantially equivalent to that of the reference device(K182194). Ø6.2 with length 16.0mm is substantially equivalent to that of the reference device(K212533). Implant body feature except the texture with grooves is same as predicate device (K170608). The texture with grooves is same with Reference device (C).

The INOSS Abutment, as the subject device, is substantially equivalent to the predicate device (K170608), reference device (K210826), reference device (K182081), reference device (K222636), reference device (K172100), and reference device (K161689) with respect to raw materials, dimensions, surface treatment, and sterilization.

In the case of Cover Screw as subject device, Ø3.5 is substantially equivalent to that of predicate device(K170608) and Ø4.5 and Ø5.7 are substantially equivalent to that of reference device(K210826) for diameter. Length 5.1mm is substantially equivalent to that of predicate device(K170608). The surface treatment of Cover Screw as subject device is substantially equivalent to that of reference device(K210826). The raw material and sterilization are substantially equivalent to that of predicate device(K170608).

In the case of Healing Abutment as subject device, Ø3.5, Ø4.0, Ø4.5 are substantially equivalent to that of reference device(K182081) and Ø5.0, Ø5.5, Ø5.9, Ø6.5, Ø7.0 are substantially equivalent to that of predicate device(K170608) for diameter. Height 3mm, 5mm, 7mm(x Ø3.5, Ø4.5) and Height 3mm, 4mm, 5mm, 6mm, 7mm(x Ø4.0) are substantially equivalent to that of reference device(K182081). Height 3mm, 4mm, 5mm, 6mm, 7mm(x Ø5.0, Ø5.9, Ø7.0) and Height 3mm, 5mm, 7mm(x Ø5.5, Ø6.5) are substantially equivalent to that of predicate device(K170608). The material, surface treatment and sterilization are substantially equivalent to that of predicate device(K170608).

In the case of Stock Abutment as subject device, all size range is substantially equivalent to that of the predicate device(K170608). The raw material and surface treatment is substantially equivalent to that of reference device(K222636). The sterilization is substantially equivalent to that of predicate device(K170608).

In the case of Abutment Screw, the diameter, raw material, surface treatment and sterilization are substantially equivalent to that of the reference device(K172100). The length is substantially equivalent to that of reference device(K161689).

Since the features of the subject device are substantially equivalent to the above-mentioned devices, any minor differences in certain features compared to the predicate device are insignificant and do not affect the determination of substantial equivalence.

[Comparison between Subject and Predicate Device]

1) INOSS Fixture

FEATURE	Subject device	Predicate device	Reference device (A)	Reference device (B)	Reference device (C)	Comparison Discussion
510(k) Number	*Not applicable*	K170608	K182194	K212533	K163194	*Not applicable*
Company Name	INOSYS, INC.	DIO Corporation	DIO Corporation	Institut Straumann AG	JJGC Industria e Comercio de Materiais Dentarios SA	*Not applicable*
Trade Name	INOSS System	UF(II) Implant System	UV Active Implant System	BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants	Neodent Implant System - GM Line	*Not applicable*
Reason for Predicate Device	*Not applicable*	Indications for use, Prosthetic Interface Connection, Implant Body Diameter & Length, Material, Surface Treatment, Sterilization, Implant Body Feature	Implant Body Diameter & Length	Implant Body Diameter & Length	Implant Body Feature	*Not applicable*
Product Code	DZE , NHA	DZE , NHA	DZE , NHA	DZE	DZE , NHA	*Not applicable*
Indications for Use	INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System 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	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	The UV Active 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 narrow (Ø3.0, Ø3.3) implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. It is intended for delayed loading. The Regular (Ø3.8 ~	Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good	Indications for Use for GM implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit	The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging connection. Therefore, its Indications for Use are limited to "a root form means for single-units' prosthetic attachment to restore a patient's chewing function."

FEATURE	Subject device	Predicate device	Reference device (A)	Reference device (B)	Reference device (C)	Comparison Discussion
	when good primary stability is achieved with appropriate occlusal loading.	surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading.	Ø5.5) implants 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. The Wide (Ø5.9 ~ Ø6.4) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	primary stability is achieved and with appropriate occlusal loading to restore chewing function.	restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for GM Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for GM Pro Peek Abutments: The Pro PEEK Abutments are	In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as “a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function.” There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System). The differences in the indications for use between the subject and predicate devices do not substantively alter their intended use and therefore do not impact the Substantial Equivalence determination.

FEATURE	Subject device	Predicate device	Reference device (A)	Reference device (B)	Reference device (C)	Comparison Discussion
					indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	
Prosthetic Interface Connection	Hex	Hex	Hex	TorcFit (with conical fitting)	GM interface; 16° Morse taper with anti-rotational features	Same as predicate device (K170608)
Implant Body Diameter & Length	· Ø3.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm · Ø4.3 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm · Ø4.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm · Ø5.4 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm · Ø6.2 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm	· Ø3.8 : 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm, 16.0mm · Ø4.0 : 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm, 16.0mm · Ø4.5 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm, 16.0mm · Ø5.0 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm, 16.0mm · Ø5.5 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm, 16.0mm	· Ø3.0 : 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø3.3 : 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø3.8 : 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø4.0 : 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø4.5 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø5.0 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø5.5 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø5.9 : 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm · Ø6.4 : 7.0mm, 8.5mm,	· Ø5.0 : 18mm · Ø5.5 : 14mm, 16mm · Ø6.5 : 14mm, 16mm	· Ø3.5 : 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm · Ø4.3 : 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm · Ø5.0 : 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm	(Ø3.9, Ø4.3 : 8.0mm, 10mm, 11.5mm, 13.0mm, 16.0mm) Ø3.9, Ø4.3 with all length is covered by reference device (C). (Ø4.9, Ø5.4 : 8.0mm, 10mm, 11.5mm, 13.0mm, 16.0mm) Ø4.9, Ø5.4 with all length is covered by predicate device. (Ø6.2 : 8.0mm, 10mm, 11.5mm, 13.0mm) Ø6.2 with 8.0mm to 13.0mm is covered by Reference device (A). (Ø6.2 : 16.0mm) Ø6.2 with 16.0mm is covered by Reference device (B).

FEATURE	Subject device	Predicate device	Reference device (A)	Reference device (B)	Reference device (C)	Comparison Discussion
			10.0mm, 11.5mm, 13.0mm			
Material	Unalloyed Titanium Grade 4 (ASTM F67)	Unalloyed Titanium Grade 4 (ASTM F67)	Unalloyed Titanium Grade 4 (ASTM F67)	Titanium-13 Zirconium alloy (Roxolid®)	Unalloyed Titanium Grade 4 (ASTM F67)	Same as predicate device (K170608)
Surface Treatment	SAT (Sandblasted Acid-etched Treatment)	SLA (Sand-blasted, Large grit, Acid-etched)	SLA	Hydrophilic SLActive® and SLA®	Neoporos, Acqua	Same as predicate device (K170608)
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Irradiation	Gamma irradiation	Same as predicate device (K170608)
Implant Body Feature	· Tapered Body · Cutting Edge with self-tapping · Thread Type · Apical Design · Texture with grooves	· Tapered Body · Cutting Edge with self-tapping · Thread Type · Apical Design	· Internal Type and Morse Tapered	· Tapered body	· Titamax · Helix · Drive (Texture with grooves)	Implant body feature except texture with grooves is same as predicate device (K170608). The texture with grooves is same as GM Drive implants of Reference device (C).

2) Cover Screw

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
510(k) Number	*Not applicable*	K170608	K210826	*Not applicable*
Company Name	INOSYS, INC.	DIO Corporation	MegaGen Implant Co., Ltd.	*Not applicable*
Trade Name	INOSS System	UF(II) Implant System	Healing Abutment, Cover Screw	*Not applicable*
Reason for Predicate Device	*Not applicable*	Indications for use, Diameter, Length, Material, Sterilization	Diameter, Surface Treatment	*Not applicable*
Product Code	DZE , NHA	DZE , NHA	NHA	Not applicable
Indications for Use	INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System can be placed with a	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)	MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.	The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
	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.	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.		connection. Therefore, its Indications for Use are limited to "a root form means for single-units' prosthetic attachment to restore a patient's chewing function." In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as "a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function." There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System). The differences in the indications for use between the subject and predicate devices do not substantively alter their intended use and therefore do not impact the Substantial Equivalence determination.
Diameter	Ø3.5, Ø4.5, Ø5.7	Ø2.7, Ø2.794, Ø3.6, Ø 3.8	Ø 6.0	(Diameter Ø3.5) Ø3.5 is covered by diameter of predicate device. (Diameter Ø4.5, Ø5.7) Ø4.5, Ø5.7 are coverd by reference device.
Length	5.1mm	4.7mm, 5.7mm, 6.3mm, 6.5mm, 7.3mm, 7.5mm, 8.1mm, 9.1mm	7.2mm ~ 8.3mm	This is covered by predicate device.
Material	Unalloyed Titanium Grade 4 (ASTM F67)	Unalloyed Titanium Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	Same as predicate device
Surface Treatment	Machined surface	Anodizing	Machined surface	Similar as Reference device
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Similar as predicate device

3) Healing Abutment

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
510(k) Number	*Not applicable*	K170608	K182081	*Not applicable*
Company Name	INOSYS, INC.	DIO Corporation	J Dental Care S.r.l.	*Not applicable*
Trade Name	INOSS System	UF(II) Implant System	JDentalCare® Implant System JDIcon®	*Not applicable*
Reason for Predicate Device	*Not applicable*	Indications for use, Diameter, Height, Material, Surface Treatment, Sterilization	Diameter, Height	*Not applicable*
Product Code	DZE , NHA	DZE , NHA	DZE, NHA	Not applicable
Indications for Use	INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System 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.	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.	JDentalCare® implant system JDIcon® is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible. JDentalCare® implant system JDIcon® is comprised of dental implant fixtures and prosthetic devices. It provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. JDentalCare® implant system JDicon® 2.75mm D	The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging connection. Therefore, its Indications for Use are limited to “a root form means for single-units' prosthetic attachment to restore a patient's chewing function.” In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as “a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function.” There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System). The differences in the indications for use between the subject and predicate devices do not substantively alter

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
			Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single-stage or two-stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.	their intended use and therefore do not impact the Substantial Equivalence determination.
Diameter	Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø5.9, Ø6.5, Ø7.0	Ø4.6, Ø4.7, Ø5.6, Ø6.6, Ø7.6	Ø3.2, Ø4.0, Ø5.0, Ø6.0	(Diameter Ø3.5, Ø4.0, Ø4.5) These are covered by reference device. (Diameter Ø5.0, Ø5.5, Ø5.9, Ø6.5, Ø7.0) These are covered by predicate device.
Height	• Ø3.5, Ø4.5 : 3mm, 5mm, 7mm • Ø4.0 : 3mm, 4mm, 5mm, 6mm, 7mm • Ø5.0, Ø5.9, Ø7.0 : 3mm, 4mm, 5mm, 6mm, 7mm • Ø5.5, Ø6.5 : 3mm, 5mm, 7mm	2mm, 4mm, 5.5mm, 7mm	3mm, 5mm, 7mm	(Height 3mm, 5mm, 7mm(x Ø3.5, Ø4.5)) & (Height 3mm, 4mm, 5mm, 6mm, 7mm(x Ø4.0)) These are covered by reference device. (Height 3mm, 4mm, 5mm, 6mm, 7mm(x Ø5.0, Ø5.9, Ø7.0)) & (Height 3mm, 5mm, 7mm(x Ø5.5, Ø6.5)) These are covered by predicate device.
Material	Unalloyed Titanium Grade 4 (ASTM F67)	Unalloyed Titanium Grade 4 (ASTM F67)	Titanium Grade 5	Same as predicate device
Surface Treatment	Machined surface	Machined surface	*Not stated in 510(k) Summary*	Similar as predicate device
Sterilization	Gamma sterilization	Gamma sterilization	Non sterile	Similar as predicate device

4) Stock Abutment

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
510(k) Number	*Not applicable*	K170608	K222636	*Not applicable*
Company Name	INOSYS, INC.	DIO Corporation	Hiossen Inc.	*Not applicable*
Trade Name	INOSS System	UF(II) Implant System	ET Abutment System	*Not applicable*
Reason for Predicate Device	*Not applicable*	Indications for Use, Diameter, Height, Sterilization	Material, Surface Treatment	*Not applicable*
Product Code	DZE , NHA	DZE , NHA	NHA	Not applicable
Indications for Use	INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System 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.	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.	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging connection. Therefore, its Indications for Use are limited to “a root form means for single-units' prosthetic attachment to restore a patient's chewing function.” In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as “a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function.” There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System). The differences in the indications for use between the subject and predicate devices do not

FEATURE	Subject device	Predicate device	Reference device	Comparison Discussion
				substantively alter their intended use and therefore do not impact the Substantial Equivalence determination.
Diameter	Ø4.5, Ø5.5, Ø6.5	Ø4.5, Ø5.5, Ø6.5, Ø7.5	4.0 ~ 7.0mm	These are covered by predicate device.
Height	5.5mm	4.0mm, 5.5mm, 7.0mm	4.0mm, 5.5mm, 7.0mm	These are covered by predicate device.
Material	Ti-6Al-4V ELI (ASTM F136)	Unalloyed Titanium Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	Same as reference device
Surface Treatment	Machined surface	TiN Coating	Machined surface	Similar as reference device
Sterilization	User Moist Heat Sterilization (Delivered non sterilie)	Steam Sterilization by user (Delivered non sterilie)	• Delivered non-sterilized • Steam sterilized by user	Similar as predicate device

5) Abutment Screw

FEATURE	Subject device	Reference device (A)	Reference device (B)	Comparison Discussion
510(k) Number	*Not applicable*	K172100	K161689	*Not applicable*
Company Name	INOSYS, INC.	TruAbutment Inc.	OSSTEM Implant Co., Ltd.	*Not applicable*
Trade Name	INOSS System	URIS OMNI System	OSSTEM Implant System - Abutment	*Not applicable*
Reason for Reference device	*Not applicable*	Indications for Use, Diameter, Material, Surface Treatment, Sterilization	Length	*Not applicable*
Product Code	DZE , NHA	DZE , NHA	NHA	Not applicable
Indications for Use	INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System can be placed with a conventional two stage surgical process with an option for	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multipleunit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The Indications for Use of the subject and predicate devices are substantially equivalent to that of predicate device(K170608). However, the subject device includes only an engaging connection and does not provide a non-engaging connection. Therefore, its Indications for Use are limited to “a root form means for

FEATURE	Subject device	Reference device (A)	Reference device (B)	Comparison Discussion
	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.			single-units' prosthetic attachment to restore a patient's chewing function." In contrast, the predicate device provides both engaging and non-engaging connections, and its Indications for Use are described as "a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function." There is also a slight difference in the Trade Names referenced (Subject device : INOSS System , Predicate device : UF(II) Implant System). The differences in the indications for use between the subject and predicate devices do not substantively alter their intended use and therefore do not impact the Substantial Equivalence determination.
Diameter	Ø1.95	Ø1.9, Ø2.3	Ø2.0, Ø2.05, Ø2.2, Ø2.3, Ø2.5	(Diameter Ø1.95) This is covered by reference device (A).
Length	8.2mm	7.2mm, 7.7mm	3.35mm, 5.6mm, 7.5mm, 8.35mm, 9.6mm, 10.2mm	(Length 8.2mm) This is covered by reference device (B).
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Same as reference device (A)
Surface Treatment	Machined surface	Machined surface	*Not stated in 510(k) Summary*	Similar as reference device (A)
Sterilization	User Moist Heat Sterilization (Delivered non sterilie)	Non-sterile (Sterilized by end user)	*Not stated in 510(k) Summary*	Similar as reference device (A)

Non-clinical test data

The following tests were performed for the subject device :

• Bacterial endotoxin testing (LAL) in accordance with ANSI/AAMI ST72:2019 and USP 43 <85>

• For the implant bodies, Biocompatibility testing in accordance with ISO 10993-1:2018 : Cytotoxicity in accordance with ISO 10993-5:2009, Intracutaneous Irritation in accordance with ISO 10993-23:2021, Maximization sensitization in accordance with ISO 10993-10:2021.
Biocompatibility for the abutments is leveraged from K220390.

• Gamma radiation sterilization validation in accordance with ANSI/AAMI/ISO 11137-1: 2006/ (R) 2015 & A1:2013 & A2:2019 , ISO 11137-2 Third edition 2013-06 [including AMD1:2022] , ANSI/AAMI/ISO 11137-3:2017/(R)2023 , ISO 11737-1 Third edition 2018-01 [Including AMD1:2021] , ANSI/AAMI/ISO 11737-2:2019, and AAMI TIR17:2017/(R)2020.

• User moist heat sterilization validation in accordance with ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020, ISO 17665-1:2006, ISO/TS 17665-2:2009, ISO 11138-1:2017, ISO 11737-1:2018/Amd 1:2021, and ISO 11737-2:2019

• Shelf life testing(Aging study) in accordance with ISO 11607-1:2019/Amd 1:2023, ASTM F1980-21, ASTM F88/F88M-23, ASTM F2096-11(2019), sterility test(USP 71), and ASTM F1886/F1886M-16

• Implant surface characterization was conducted utilizing Scanning Electron Microscopy(SEM)/Energy Dispersive Spectrometry(EDS) methodologies

• MR Environment Condition
Non-Clinical worst-case MRI review was performed to evaluate the INOSS System devices in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. Journal of Testing and Evaluation 49.2, 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

The results of the non-clinical testing confirm that the subject device meets the criteria of the applicable standards and is substantially equivalent to the predicate device.

No clinical data were included in this submission.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807, and based on the information provided in this premarket notification, INOSYS, INC. concludes that the INOSS System is substantially equivalent to the above-mentioned currently cleared devices.

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