December 22, 2025

DIMPLO Ltd.
Jiyeon Sung
2F, 16, Hwangsaeal-ro, Yeonje-gu
Busan, 47507
REPUBLIC OF KOREA

Re: K251605
Trade/Device Name: DIMPLO Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 30, 2025
Received: December 5, 2025

Dear Jiyeon Sung:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K251605

Device Name

DIMPLO Implant System

Indications for Use *(Describe)*

The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved.
- Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only.
- Ø5.0 mm and larger implants are intended for delayed loading in the molar region.

All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K251605

Date Prepared: December 19, 2025

I. SUBMITTER

DIMPLO Ltd.
Jiyeon Sung
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Busan, Republic of Korea
Phone: +82-51-503-2885
Fax: +82 51 504 2885

II. DEVICE

- Trade Name: DIMPLO Implant System
- Common Name: Endosseous dental implant, Endosseous dental implant abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: DZE, NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II

III. PREDICATE DEVICE

1. Primary Predicate (Submission Number / Applicant / Trade Name)
- K181138 / Neobiotech Co., Ltd. / IS-III active System

2. Predicate/Reference Device (Submission Number / Applicant / Trade Name)
- K161987 / UF(II) Narrow Implant System / DIO Corporation
- K141457 / DENTIUM CO. LTD. / DENTIUM IMPLANTIUM AND SUPERLINE ABUTMENTS
- K231426 / HOOWON EDI Co., Ltd. / 8palnt Implant System
- K161689 / OSSTEM Implant Co., Ltd. / OSSTEM Implant System - Abutment
- K223924 / Ossvis Co., Ltd. / LW Implant System
- K231753 / Oneday Biotech Co., Ltd. / Oneday Implant Abutment
- K231411 / Cowellmedi Co., Ltd. / INNO SLA Submerged Hybrid Ti-Base System
- K220253 / DIO Corporation / Eco Abutment, Multiunit Abutment
- K210117 / Paltop Advanced Dental Solutions, Ltd / Paltop Narrow Implant
- K231395 / Cowellmedi Co., Ltd. / INNO SLA Submerged Narrow Implant System
- K201323 / Cowellmedi Co., Ltd. / Sonator Abutment for INNO SLA Submerged Implant System
- K161713 / Dentium Co., Ltd / Dentium CAD/CAM Abutments

IV. DEVICE DESCRIPTION

The DIMPLO Implant System consists of fixtures, abutments, and attachments designed for dental implant procedures.
Fixture: Made of unalloyed titanium (Grade 4, ASTM F67), these dental implants are available in a range of diameters and lengths to accommodate various clinical applications in the maxilla and mandible. The surface is treated with SLA (Sandblasted, Large grit, and Acid-etched) and provided sterile via gamma irradiation. Available in two platform sizes: Mini and Regular.
Abutment: These components aid in prosthetic restorations. This category includes Cover Screws, Healing Abutments, Temporary Abutments, Cemented Abutments, Angled Abutments, Ti-Base, Pre-milled Blanks, Screws, Multi-unit Abutments, Healing Caps, and Cylinders.
Attachments: Includes Locatus Male Cap and Locatus Retention Male. The Locatus Male Cap is made of titanium alloy (Ti-6Al-4V ELI), while the Locatus Retention Male is made of nylon.
Fixtures and cover screws are supplied sterile. All other abutments and attachments are provided non-sterile and must be sterilized by the end user before use.

Ti-Base consists of a two-piece abutment that includes a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient-specific superstructure) at the top, composing the final abutment.

* Superstructure and Bonding Materials

- Zirconia material: InCoris Zi (ZrO_2) (K123664, Sirona Dental Systems GmbH)
- Bonding agent: RelyX Unicem 2 Automix (K100756, 3M ESPE)

Design Envelope for Zirconia superstructure

Dimensional Characteristics	Range/Limit
Post Angle (°)	0~20
Cuff Height (mm)	0.5~5.0
Abutment Post Height (mm)	4.0~6.0
Diameter (Ø, mm)	5.0~8.0
Wall Thickness (mm)	0.4~

- Design Envelope for Pre-milled Blank

Dimensional Characteristics	Range/Limit
Post Angle (°)	0~30
Cuff Height (mm)	0.5~6.0
Abutment Post Height (mm)	4.0~7.0
Diameter (Ø, mm)	3.5~6.5
Wall Thickness (mm)	0.4~

* Note: Abutment Post Height is defined as the minimum cementable post height for single-unit restoration, measured as the height above the restorative margin.

V. INDICATIONS FOR USE

The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved.
- Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only.
- Ø5.0 mm and larger implants are intended for delayed loading in the molar region.

All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Fixture

	Subject Device	Primary Predicate Device	Reference Predicate Device
510(k) No.	K251605	K181138	K161987
Applicant	DIMPLO Ltd.	Neobiotech Co., Ltd.	DIO Corporation
Device Name	DIMPLO Implant System	IS-III active System	UF(II) Narrow Implant System
Classification Name	Endosseous Dental Implant, Fixture (872.3640)	Endosseous Dental Implant, Fixture (872.3640)	Endosseous Dental Implant, Fixture (872.3640)
Product Code	DZE	DZE	DZE
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.	The UF(II) Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.0mm, 3.3mm diameter UF(II) Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.
Diameter x Lengths(mm)	Ø3.3 X 8.5, 10, 11.5, 13, 15 Ø3.75 X 8.5, 10, 11.5, 13, 15 Ø4.25 X 8.5, 10, 11.5, 13, 15 Ø4.6 X 8.5, 10, 11.5, 13, 15 Ø5.05 X 8.5, 10, 11.5, 13, 15 Ø5.45 X 8.5, 10, 11.5, 13 Ø5.95 X 8, 9.5, 11, 12.5 Ø6.8 X 8, 9.5, 11, 12.5	Ø3.5 X 8.5, 10, 11.5, 13, 15 Ø4.0 X 7.3, 8.5, 10, 11.5, 13, 15 Ø4.5 X 7.3, 8.5, 10, 11.5, 13, 15 Ø5.0 X 7.3, 8.5, 10, 11.5, 13, 15 Ø5.5 X 7.3, 8.5, 10, 11.5, 13, 15 Ø6.0 X 7.3, 8.5, 10, 11.5, 13 Ø7.0 X 7.3, 8.5, 10, 11.5, 13	Ø3.0 X 8.5, 10, 11.5, 13, 15 Ø3.3 X 8.5, 10, 11.5, 13, 15
Connection Interface	Internal Hex	Internal Hex	Internal Hex

Surface Treatment	SLA	SLA	SLA
Sterile	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf Life	5 years	5 years	5 years
Substatial Equivalence	The subject device has the same intended use, material, abutment-implant interface, surface treatment, sterilization method, and shelf life as the primary predicate device(K181138), and the reference predicate(K161987). The implant diameters and lengths of the subject device are within or comparable to those of the predicate devices and do not raise new questions regarding safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate devices.		

Cover Screw

	Subject Device	Predicate Device
510(k) No.	-	K141457
Applicant	DIMPLO Ltd.	DENTIUM CO. LTD.
Device Name	DIMPLO Implant System	DENTIUM IMPLANTIUM AND SUPERLINE ABUTMENTS–Cover Screw
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.
Diameter(mm)	3.03~3.88	3.6
Angulation	0	0
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	The Subject Device and the predicate device(K141457) have equivalent characteristics, including Indications for Use, material, angulation, and sterilization method. The difference in diameter size does not impact the product's fundamental technology. Therefore, the Subject Device and the predicate device are substantially equivalent.	

Healing Abutment

	Subject Device	Predicate Device
510(k) No.	K251605	K231426
Applicant	DIMPLO Ltd.	HOOWON EDI Co., Ltd.
Device Name	DIMPLO Implant System	8palnt Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are	8 plant Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implant bodies with a diameter of 5mm or more are intended to be used in the molar region.

	achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. ll digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	
Diameter(mm)	4.3, 4.8	4.3,4.8,5.3,5.8,6.3,7.3,8.3
Gingival Height (mm)	3,4,5,6,7,9	1.0 ~ 12.0
Angulation(°)	0	0
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Principle of operation	This component is intended to protect the inner configuration of the implant during the healing process and maintain, stabilize and form the soft tissue during this phase.	This component is intended to protect the inner configuration of the implant during the healing process and maintain, stabilize and form the soft tissue during this phase.
Substatial Equivalence	The Subject Device and the predicate device(K231426) have equivalent characteristics, including Indications for Use, material, angulation, sterilization method, abutment-implant interface, and principle of operation. Differences in diameter size and gingival height do not impact the product's fundamental technology. Therefore, the Subject Device and the predicate device are substantially equivalent.	

Temporary Abutment

	Subject Device	Predicate Device
510(k) No.	K251605	K161689
Applicant	DIMPLO Ltd.	OSSTEM Implant Co., Ltd.
Device Name	DIMPLO Implant System	OSSTEM Implant System - Abutment
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Surface Treatment	None	None
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	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.
Diameter(mm)	4.1, 4.6	4.0, 4.5
G/H(mm)	1.0, 3.0	1.0, 3.0
Post Height(mm)	10	10
Angulation(°)	0	0
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Maximun duration	Less than 6 months	Less than 6 months
Principle of operation	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a

	permanent crown is made.	permanent crown is made.
Substatial Equivalence	The subject device and the predicate device (K161689) have equivalent material, abutment-implant interface, surface treatment, sterilization state, and principle of operation. Both devices are intended for temporary clinical use during the healing process until a permanent prosthesis is placed. The maximum recommended duration of use for the subject device is the same as the predicate device, limited to less than 6 months. Therefore, the subject device is substantially equivalent to the identified predicate device.	

Cemented Abutment

	Subject Device	Predicate Device
510(k) No.	K251605	K223924
Applicant	DIMPLO Ltd.	Ossvis Co., Ltd.
Device Name	DIMPLO Implant System	LW Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Surface Treatment	None	None
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The LW Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The LW Implant System is dedicated for two stage surgical procedures and is intended for delayed loading. Also, implants with diameters larger than 5mm are indicated for molar regions.
Diameter(mm)	4.6, 5, 6, 7	4.5, 4.6, 5.0, 6.0, 7.0
G/H(mm)	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Post(mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0
Angulation(°)	0	0
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Principle of operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.
Substatial Equivalence	The subject device and the predicate device (K223924) have equivalent indications for use as both screw-retained and cement-retained abutments in partially or fully edentulous patients. Both devices have the same material, abutment-implant interface, sterilization state, and principle of operation. The subject device does not include the 4.5 mm diameter available in the predicate device; all other diameters are equivalent. Therefore, the subject device is substantially equivalent to the predicate device.	

Angled Abutment

	Subject Device	Predicate Device
510(k) No.	-	K231753
Applicant	DIMPLO Ltd.	Oneday Biotech Co., Ltd.
Device Name	DIMPLO Implant System	Oneday Implant Abutment
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA

Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.
Diameter(mm)	4, 4.5, 5, 6	4, 4.5, 5, 5.5, 6, 7, 8
Length(mm)	12.5~14.5	9.7, 10.7, 11.7, 12.7
Angulation(°)	17	15, 25
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile(End User Sterilization)	Non-sterile(End User Sterilization)
Principle of operation	This product is a superstructure which is connects with the fixtures. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures. It replaces the functions of the missing teeth as a dental abutment.
Substatial Equivalence	The subject device and the predicate device(K231753) have equivalent indications for use, material, abutment-implant interface, sterilization, and principle of operation. Differences in diameter (within the predicate's range), length, and angulation (17° for the subject device versus 15° and 25° for the predicate) do not impact equivalence. Therefore, the subject device is substantially equivalent to the predicate device.	

Ti-Base

	Subject Device	Predicate Device
510(k) No.	-	K231411
Applicant	DIMPLO Ltd.	Cowellmedi Co., Ltd.
Device Name	DIMPLO Implant System	INNO SLA Submerged Hybrid Ti-Base System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	INNO SLA Submerged Hybrid Ti-Base System is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. Digitally All digitally designed zirconia superstructures for use with the INNO SLA Submerged Hybrid Ti-Base System are intended to be sent to a Cowellmedi validated milling center for manufacture.
Design Limits	- Post Angle (°): 0~20 - Cuff Height (mm): 0.5~5.0 - Abutment Post Height (mm): 4.0~6.0	Maximum Angulation 20° Maximum Cuff Height 5.0mm Minimum Gingival Height, 0.5mm

	- Diameter (Ø, mm): 5.0~8.0 - Thickness (mm): 0.4~ * Note: Abutment Post Height is defined as the minimum cementable post height for single-unit restoration, measured as the height above the restorative margin.	Minimum Diameter Ø 5.0mm Minimum Thickness 0.4mm Minimum Abutment Post Height 4.0mm
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	Both the subject device and predicate device(K231411) share equivalency in indications for use, material, abutment-implant interface, sterilization, design limit and restoration compatibility. Accordingly, the subject device is substantially equivalent to the predicate device.	

Multi-unit Abutment

	Subject Device	Predicate Device
510(k) No.	-	K220253
Applicant	DIMPLO Ltd.	DIO Corporation
Device Name	DIMPLO Implant System	Eco Abutment, Multiunit Abutment
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The Multiunit Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.
Diameter(mm)	4.8, 4.9	4.8
Gingival Height (mm)	1.5, 2.5, 3.5, 4.5, 5.5, 6.5, 7.5	2.5, 3.0, 3.5, 4.5 ,5.5 ,6.5 ,7.5
Angulation(°)	0, 17, 30	0, 20, 30
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Principle of operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.
Substatial Equivalence	The subject device and predicate device(K220253) are equivalent in indications for use, material, abutment-implant interface, sterilization, and restoration. Variations in diameter, gingival height, and angulation do not impact the device's equivalence. Hence, the subject device and predicate device are substantially equivalent.	

Healing Cap

	Subject Device	Predicate Device
510(k) No.	-	K210117
Applicant	DIMPLO Ltd.	Paltop Advanced Dental Solutions, Ltd
Device Name	DIMPLO Implant System	Paltop Narrow Implant-w/Healing Cap
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)

Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The Paltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Diameter(mm)	4.8	5
Height (mm)	4.6	1,2,3,4,5
Angulation(°)	0	0
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	The subject device and predicate device(K210117) are equivalent in indications for use, material, sterilization, and angulation. The differences in diameter and height do not affect substantial equivalence. Therefore, the subject device and predicate device are substantially equivalent.	

Cylinder Screw

	Subject Device	Predicate Device
510(k) No.	-	K231395
Applicant	DIMPLO Ltd.	Cowellmedi Co., Ltd.
Device Name	DIMPLO Implant System	INNO SLA Submerged Narrow Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The INNO SLA Submerged Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.3mm, 3.5mm diameter Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.
Diameter(mm)	2.15	2.25
Length(mm)	3.9	5
Sterile	Non-sterile	Non-sterile
Principle of operation	Multi-unit Cylinder Screw is a premanufactured prosthetic component directly connected to the Multi-unit Abutment and is intended for use as an aid in prosthetic rehabilitation.	Multi-unit Cylinder Screw is a premanufactured prosthetic component directly connected to the Multi-unit Abutment and is intended for use as an aid in prosthetic rehabilitation.
Substatial	The subject device and predicate device(K231395) are equivalent in indications for use, material, sterilization, and principle of	

Equivalence	operation. Differences in diameter and length do not affect the equivalency of the devices. As such, the subject device is substantially equivalent to the predicate device.

Temporary Cylinder

	Subject Device	Predicate Device
510(k) No.	-	K231395
Applicant	DIMPLO Ltd.	Cowellmedi Co., Ltd.
Device Name	DIMPLO Implant System	INNO SLA Submerged Narrow Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The INNO SLA Submerged Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.3mm, 3.5mm diameter Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.
Diameter(mm)	4.8, 5.3	4.5
Height (mm)	12	9
Angulation(°)	0	0
Sterile	Non-sterile	Non-sterile
Principle of operation	This is designed to serve as a temporary dental prosthesis during the healing process until a permanent are made.	This is designed to serve as a temporary dental prosthesis during the healing process until a permanent are made.
Duration of use	90days	90days
Substatial Equivalence	Equivalent characteristics between the subject device and predicate device(K231395) include indications for use, material, sterilization, principle of operation, angulation, and duration of use. Variations in diameter and height do not alter substantial equivalence. Therefore, the subject device is substantially equivalent to the predicate device.	

Ti Cylinder

	Subject Device	Predicate Device
510(k) No.	-	K231395
Applicant	DIMPLO Ltd.	Cowellmedi Co., Ltd.
Device Name	DIMPLO Implant System	INNO SLA Submerged Narrow Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved.	The INNO SLA Submerged Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.3mm, 3.5mm diameter Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.

	- Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	
Diameter(mm)	5	4.5
Height (mm)	4.3, 6.3	4.5
Angulation(°)	0	0
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	The subject device and predicate device(K231395) have equivalent indications for use, material, sterilization, and angulation. Differences in diameter and height do not affect substantial equivalence. Accordingly, the subject device and predicate device are substantially equivalent.	

Locatus

	Subject Device	Predicate Device
510(k) No.	-	K201323
Applicant	DIMPLO Ltd.	Cowellmedi Co., Ltd.
Device Name	DIMPLO Implant System	Sonator Abutment for INNO SLA Submerged Implant System
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screwretained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Diameter(mm)	3.86	3.87, 4.5
Gingival Height (mm)	1, 2, 3, 4, 5, 6, 7	1, 1.5, 2, 3, 4, 5, 6
Angulation(°)	0,	0, 15
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Principle of operation	This component is used for implantretained muscosa-supported restorations, such as dentures. It supports implant retained mucoss supported over dentures.	This component is used for implantretained muscosa-supported restorations, such as dentures. It supports implant retained mucoss supported over dentures.
Substatial Equivalence	Equivalent characteristics between the subject device and predicate device(K201323) include indications for use, material, sterilization, and principle of operation. Variations in diameter, gingival height, and angulation do not impact equivalence. Therefore, the subject device is substantially equivalent to the predicate device.	

Pre-milled Blank

	Subject Device	Predicate Device

510(k) No.	-	K161713
Applicant	DIMPLO Ltd.	Dentium Co., Ltd
Device Name	DIMPLO Implant System	Dentium CAD/CAM Abutments
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	Dentium abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. All digitally designed abutments for use with Dentium CAD/CAM Abutments are intended to be sent to a Dentium-validated milling center for manufacture.
Platform Diameter(mm)	3.2 - 6.8	3.6 - 5.0
Design Limits	- Post Angle (°): 0~30 - Cuff Height (mm): 0.5~5.0 - Abutment Post Height (mm): 4.0~6.0 - Diameter (Ø, mm): 5.0~8.0 - Thickness (mm): 0.4~ * Note: Abutment Post Height is defined as the minimum cementable post height for single-unit restoration, measured as the height above the restorative margin.	Up to 30°
Abutment-Implant Interface	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	Equivalent characteristics between the subject device and predicate device(K201323) include indications for use, material, sterilization, and principle of operation. Variations in diameter, gingival height, and angulation do not impact equivalence. Therefore, the subject device is substantially equivalent to the predicate device.	

Abutment Screw

	Subject Device	Predicate Device
510(k) No.	-	K231753
Applicant	DIMPLO Ltd.	Oneday Biotech Co., Ltd.
Device Name	DIMPLO Implant System	Oneday Implant Abutment
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications for use/Intended use	The DIMPLO Implant System is intended for use in the maxilla or mandible of partially or fully edentulous patients to support single or multiple-unit restorations, including cemented, screw-retained, or overdenture restorations, as well as terminal or intermediate abutment support for fixed bridgework. It is intended for two-stage surgical procedures and may be used for immediate loading when good primary stability and appropriate occlusal loading conditions are achieved. - Ø3.3 mm implants are for replacing maxillary lateral incisors and mandibular incisors with delayed loading only. - Ø5.0 mm and larger implants are intended for delayed	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.

	loading in the molar region. All digitally designed custom components (including Ti-Base and Pre-milled Blanks) for use with the DIMPLO Implant System are to be manufactured at a DIMPLO validated milling center.	
Diameter(mm)	2.2, 2.3	2.3
Lenght(mm)	10.2, 8.35	8.3
Sterile	Non-sterile	Non-sterile
Substatial Equivalence	The subject device and predicate device(K231753) have equivalent characteristics in indications for use, material, and sterilization. Variations in diameter and length do not influence the substantial equivalency of the devices. Thus, the subject device and the predicate device are substantially equivalent.	

VII. NON-CLINICAL PERFORMANCE DATA

Non-clinical testing was performed to evaluate the safety and performance of the DIMPLO Implant System.

1. Sterilization and Shelf-Life Testing
Sterilization validation was conducted for gamma-sterilized components (e.g., fixtures) in accordance with ISO 11137-1 and ISO 11137-2. The tests to validate the Shelf-Life of the device were conducted using the accelerated aging method in accordance to ASTM F1980Shelf-life testing was conducted in accordance with the guidance provided in FDA's Shelf Life of Medical Devices Guidance Document, and endotoxin testing was conducted following ANSI/AAMI ST72. Components provided non-sterile (e.g., abutments and attachments) are intended to be steam sterilized by the end user, with sterilization validation conducted in accordance with ISO 17665-1, ISO 17665-2, and ANSI/AAMI ST79.and validated accordingly per ISO 17665 and ANSI/AAMI ST79 guidance.

2. Biocompatibility Testing
Biocompatibility testing including cytotoxicity, sensitization, and irritation testing were conducted according to ISO 10993-5, 10993-10, and 10993-23 respectively.Biocompatibility testing was conducted following ISO 10993. Specific testing was conducted per ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-10 (Irritation).

3. Material and Surface Characterization
The implant body surface was characterized using Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Spectroscopy (EDS). Characterization was also performed on the anodized surface of the devices.

4. Mechanical Testing
Mechanical testing, including static and fatigue testing, was performed per ISO 14801:2016.

5. MR Environment Condition
Non-Clinical worst-case MRI review was performed to evaluate the DIMPLO Implant 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.

No clinical data are included in this submission.

VIII. CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate and reference devices. Any differences in design or materials do not raise new questions of safety or effectiveness.

The data provided in this submission, including non-clinical performance testing, support that the subject device is substantially equivalent to the predicate and reference devices.

Specifically, the subject device:
- has the same intended use,
- operates on the same principles,
- incorporates similar basic designs,
- utilizes the same or similar materials, and
- has comparable packaging and sterilization methods.