July 09, 2025

P&A USA
℅ Chandler Thames
Director of Quality, Consultant
Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K243731
Trade/Device Name: HEXIM Implant; Samwon General Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 21, 2025
Received: June 5, 2025

Dear Chandler Thames:

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,

Sherrill Lathrop Blitzer

for Andrew 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.

Submission Number *(if known)*

K243731

Device Name

HEXIM Implant;
Samwon General Abutments

Indications for Use *(Describe)*

The Hexim Implant - The HEXIM Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The HEXIM Implant System is for two stage surgical procedures. It is intended for delayed loading.

Samwon General Abutments - Couple Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.

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.

510(K) Summary

I. SUBMITTER

P&A USA, Inc.
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President

7535 Little River Turnpike
Suite 310F
Annadale, VA

Phone: 503-314-9101
Email: pnausa7@gmail.com
Date Prepared: 07/08/2025

II. DEVICE

Trade Name: HEXIM Implant
Classification Name: Implant, Endosseous, Root-Form
Manufacturer Name: Uniance, Inc.
Regulatory Class: II
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 872.3640

III. PREDICATE DEVICE

a. HEXIM Implant

Tapered Screw-Vent® M Implants/ Zimmer Dental Inc. (K111889 Primary Predicate)
AR_N SLA Type Implant System/ Biotemp Co., Ltd. (K190641 Reference Device)

b. Samwon General Abutment

S-Plant Dental Implant System/ IDIS Co, Ltd. (K221866 Reference Device)

SNUCONE Tissue Level Implant System / SNUCONE Co., LTD. (K222792 Reference Device)

IV. DEVICE DESCRIPTION

The HEXIM Implant with Samwon General Abutments is a Root-form Endosseous Dental Implant and Endosseous Dental Abutment system designed for use in dental implant surgery. These devices have special controls as described by the document: *Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance for Industry and FDA Staff*.

The HEXIM Implant is a threaded root-form endosseous dental implant with an internal hexagon connection. The HEXIM implants are surgically inserted into the upper and/or lower jawbone to provide a stable foundation for restorations. Geometrically, the implant is screw type. It has external self-tapping threads with chip pocket vertical flutes to facilitate implantation. The HEXIM implant also includes a cavity which extends through the bottom of the implant and connects to 5 channels running perpendicular to the implant body long axis to aid in intra bone fixation. The bottom cavity is not directly interconnected to the internal hex connection nor to the internal threading feature used to fix abutments to the implant.

The Samwon General Abutments are connected to the implant through the implant's internally threaded hole and an internal hex connection. Samwon General Abutments come in several types: Cover Screw, Healing Abutment, Hex type Couple Abutment, and Abutment Screw. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete. Healing abutments are used after osseointegration, once the cover screw is removed, to make a natural soft tissue shape before setting up prosthetics. The Hex-type Couple Abutment is designed to mate with the internal hex cavity of the endosseous implant and is fixed to the implant via an abutment screw. The Hex-type Couple Abutment is a transgingival component, which serves as the support for the artificial tooth or other prosthetic.

System Dimensions

a. HEXIM Implant

Fixture Body Diameter (mm)	4.2,4.5, 5.0, 5.5, 6.0
Fixture Length (mm)	Ø4.2: 7.0, 8.5,10,11.5,13 Ø4.5: 7.0, 8.5,10,11.5,13 Ø5.0: 7.0, 8.5,10,11.5,13 Ø5.5: 7.0, 8.5,10,11.5,13 Ø6.0: 7.0, 8.5,10,11.5,13

b. Samwon General Abutment Screw

Fixture Body Diameter (mm)	Ø 3.35

c. Samwon General Abutment Healing Abutment

Fixture Body Diameter (mm)	Ø4.5, Ø4.8, Ø5.0, Ø5.5, Ø6.5 mm
Gingival Height	3.5 – 7.5mm
Total Length (mm)	8.4 - 11.4

d. Samwon General Abutment Screw

Samwon General Abutment Screw	
Diameter	Ø 2.32mm
Length	10.7mm

General Abutment Hex Type Cover Abutment	
Body Diameter (mm)	Ø4.5, Ø4.8, Ø5.0, Ø5.5, Ø6.5
G/H (mm)	0.9,1.9,2.9,3.9
Post Height (mm)	4.0

V. INDICATIONS FOR USE

HEXIM Implant System: The HEXIM Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The HEXIM Implant System is for two stage surgical procedures. It is intended for delayed loading.

Samwon General Abutments: Couple Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover the screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.

VI. TECHNOLOGICAL CHARACTERISTICS

P&A USA submits the following information to demonstrate that the subject device *the HEXIM Implant with Samwon General Abutments*, is substantially equivalent to the following legally marketed predicate device:

HEXIM Implant

510(k) Number	Predicate Device Name/Manufacturer	Predicate/*Reference*
K111889	*Tapered Screw-Vent® M Implants/ Zimmer Dental Inc.*	Primary Predicate
K190641	*AR_N SLA Type Implant System/ Biotemp Co., Ltd.*	Reference

Samwon General Abutment

510(k) Number	Predicate Device Name/Manufacturer	Predicate/*Reference*
K221866	*S-Plant Dental Implant System/ IDIS Co, Ltd.*	Primary
K222792	*SNUCONE Tissue Level Implant System/ SNUCONE Co., LTD.*	*Reference*

The HEXIM Implant has the same intended use, indications, principle of operation, similar technological and material characteristics as the predicate device, AR_N SLA Type Implant System (K190641). The Samwon Abutments have the same intended use, indications, principle of operation, and similar technological and material characteristics as the predicate device, S-Plant Dental Implant System (K221866) and reference device SNUCONE Tissue Level Implant System (K222792). The reference device was added for the healing abutment to give an example of gingival heights from cleared devices. Comparisons of the devices can be found in Tables 1-5:

Table 1: Comparison of the Subject and Primary Predicate for HEXIM Implant

	Subject Device: *HEXIM Implant System with Samwon General Abutments*	**Primary Predicate** *Zimmer Dental Inc. Tapered Screw-Vent® M Implants* Predicate Device (K111889)	**Reference Device** *AR_N SLA Type Implant System* Reference Device (K190641)	**Comparison**
Device Name	HEXIM Implant	Tapered Screw-Vent® M Implant	AR_N SLA Type Implant System	N/A
Manufacturer	Uniance, Inc.	Zimmer Dental Inc.	Biotem Co., Ltd.	N/A
Regulation Number	872.3640	872.3640	872.3640	Same
Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous Root-Form	Implant, Endosseous, Root-Form	Same
Product Code	DZE	DZE	DZE	Same
Device Class	II	II	II	Same
OTC or Rx	Rx	Rx	Rx	Same
Indication for use	The HEXIM Implant is indicated for use in partially or fully edentulous mandibles and	The *Tapered Screw-Vent® M Implants* are designed for use in the maxilla or	AR_N SLA Type Implant System is indicated for use in partially or fully	Similar - The predicate and reference

	maxillae, in support of single or multiple-unit restorations. The HEXIM implant system is for two stage surgical procedures. It is intended for delayed loading.	mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.	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. AR_N SLA Type Implant System is for two stage surgical procedures. It is intended for delayed loading.	device's Indications for Use do not include examples of single and multiple unit restorations. The predicate and reference device's Indications for Use do also include the option for immediate or delayed loading, whereas the subject device is indicated for delayed loading only. The difference does not impact substantial equivalence.
Principle of Operation	This product is a root-type fixture which is inserted into the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	None given	None given	Different – The predicate and reference device did not explicitly describe a

				principle of operation but based on the special controls and the indications for use, we can infer they have equivalent principles of operation.
Material	CP Ti Gr4 ASTM F67	Titanium 6AI-4v	CP Ti Gr 4 ASTM F67	Similar: The predicate device is made of a different titanium alloy than the reference and subject device. However, the material is the same metal which has similar mechanical properties, corrosion resistance, and purity.
Surface Treatment	SLA	MTX Surface	SLA	Similar: The predicate device surface treatment is different than the

				predicate but is designed to perform a the same function. The reference device surface treatment is the same. This does not affect substantial equivalence.
Sterilization	Gamma irradiation	Not specified on 510k summary	Gamma irradiation	Similar: The reference and subject device have the same sterilization method. The predicate device 510k summary did not list the sterilization method.
Connection Type	Internal Hex	Internal Hex	Internal Hex	Same
Fixture Body Diameter (mm)	4.2,4.5, 5.0, 5.5, 6.0	3.7, 4.1, 4.7, 6.0	3.7, 4.2, 4.6, 5.1, 6.0	Different: The predicate and reference device's fixture body

				diameters are slightly different from the subject device's. The subject device's diameters do fall within the range of the predicate and reference device, however. These differences do not impact substantial equivalence.
Fixture Length (mm)	Ø4.2: 7.0, 8.5,10,11.5,13 Ø4.5: 7.0, 8.5,10,11.5,13 Ø5.0: 7.0, 8.5,10,11.5,13 Ø5.5: 7.0, 8.5,10,11.5,13 Ø6.0: 7.0, 8.5,10,11.5,13	8, 10, 11.5, 13, 16	7.5, 8.5, 10, 11.5, 13, 15	Different: The subject device and predicate and reference device have similar lengths. While the shortest length of the subject device is outside the length of the predicate and reference

				device (7.0mm compared to 8mm, 7.5mm), the shorter length does not affect the safety or efficacy of the device.
Presence of Bottom Cavity	The HEXIM implant has a cavity which extends through the bottom of the implant and connects to 5 channels running perpendicular to the implant body long axis to aid in intra bone fixation. The bottom cavity is not directly interconnected to the internal hex connection nor to the internal threading feature used to fix abutments to the implant.	The *Tapered Screw-Vent® M Implants* have a cylindrical cavity that extends to the bottom of the implant.	Absence of Bottom Cavity	Similar: The subject device and predicate device both have cavities that extend through the bottom of the implant. The reference device does not have a bottom cavity.
Similarities	• The HEXIM implant system matches Tapered Screw-Vent® M Implants in base material and connection type. • The HEXIM implant system matches the *AR_N SLA Type Implant System* in material, surface finishing, sterilization method, and connection type.			
Differences	• The HEXIM implant system's diameters do not exactly match the diameters of the predicate or reference device, but its size ranges do fall within the range of those predicate and reference device and do not raise any issues regarding the safety and efficacy of the device. • The lengths of the HEXIM implant system do not exactly match the lengths of the predicate and reference device. HEXIM offers one length shorter than the predicate and reference at 7.0mm and does not offer a 15mm or 16mm length. The shorter length does not affect the safety or efficacy of the device.			

	• The exact material alloy of the HEXIM implant system do not exactly match the predicate device material alloy. However, the subject and predicate device do have the same material base and this does not affect the safety or efficacy of the device because both alloys are commonly used in dental implants as seen in the reference device. • The Principle of operation of the predicate and reference device was not given. Based on the indications for use of the predicate and the guidance document *Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance for Industry and FDA Staff* the principle of operation can be inferred as similar.

Table 2: Comparison of the Subject and Primary Predicate for Samwon General Abutment Cover Screw

	Subject Device: Samwon General abutment for use with the HEXIM Implant	**Primary Predicate** S-Plant Dental Implant System (K221866)	**Comparison**
Device Name	*Samwon General Abutment Abutment Cover Screw*	*Cover Screw for S-Plant Dental Implant System*	*N/A*
Manufacturer	*Samwon*	*IDIS Co, Ltd.*	*N/A*
Classification Name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Same
Product Code	NHA	NHA	Same
Device Class	*II*	*II*	Same
OTC or Rx	Rx	Rx	Same
Indications for use	Couple Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used	Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used	Same

	to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	
Principle of Operation	After establishing the fixation device in the alveolar bone, the screw is a standard M2.0 screw.	Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	Similar - The wording of the principle of operation achieves the same end use, but are worded differently.
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Same
Surface Treatment	None	None	Same
Sterilization	End User (Steam)	End User (Steam)	Same
Connection Type	Threaded (M2)	Threaded	Similar – All devices are threaded and are screwed into the Endosseous implant.
Fixture Body Diameter (mm)	Ø 3.35	Ø 3.6	Different - While the fixture diameters are not the same, the smaller diameter of the

			predicate does not affect the safety or efficacy of the device.
Similarities	*The subject device has similar materials, surface finish, and intended use as the identified predicate devices. Both are supplied non-sterile.*		
Differences	*The subject device's size fixture body diameter is 3.35mm while the predicates are 3.6mm. This smaller diameter does not prevent the subject device from performing.*		

Table 3: Comparison of the Subject and Primary Predicate for Samwon General Abutment Healing Abutment

	Subject Device: Samwon General abutment for use with the HEXIM Implant	**Predicate Device S-Plant Dental Implant System (**K221866)	**Reference Device** SNUCONE Tissue Level Implant System (K222792)	**Comparison**
Device Name	Samwon General Abutment Healing Abutment	Healing Abutment for the S-Plant Dental Implant System	InOcta Healing Abutment for SNUCONE Tissue Level Implant System	N/A
Manufacturer	Samwon	IDIS Co, Ltd.	SNUCONE Co., LTD.	N/A
Classification Name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Same
Product Code	NHA	NHA	NHA	Same
Device Class	II	II	II	Same
OTC or Rx	Rx	Rx	Rx	Same
Indications for Use	Couple Abutments are intended for use with a dental implant to provide support for	Dual abutments are intended for use with a dental implant to provide support for	SNUCONE Tissue Level Implant System is indicated for use in partially or fully	Subject device is the same as the predicate device. The indications are

	prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, or overdenture restorations and terminal or intermediate Abutment support for fixed bridge work. Snucone implant 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.	different from the reference device because the reference device indications for use does not specify indications for the abutments.
Principle of Operation	Before attaching the upper structure, it serves as a structure to create a more natural and aesthetically pleasing formation of the gingival tissue.	Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.	This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.	Same
Material	Ti-6Al-4V ELI of ASTM F136	Titanium Alloy	Ti-6Al-4V ELI of ASTM F136	Same

		(Ti-6Al-4V, ASTM F136)		
Surface Treatment	None	None	Anodized	The subject device's surface treatment is the same as the predicate device and different from the Reference Device.
Sterilization	End User Sterilized (Steam)	End User Sterilized (Steam)	End User Sterilized	Same
Connection Type	Threaded (M2)	Threaded	Threaded	Similar – both devices have male threading and are screwed into existing female threading in the endosseous implant.
Fixture Body Diameter (mm)	Ø4.5, Ø4.8, Ø5.0, Ø5.5, Ø6.5 mm	Ø4.0, Ø4.5, Ø5.0, Ø6.0, Ø7.0	Ø 5.5, Ø 6.1, Ø 6.3	Different – The size range of the abutments. The differences do not impact the safety or efficacy of the device.
Gingival Height	3.5 – 7.5mm	None Listed	4.0~6.5 ㎜	Different – A reference device was added to give an example of gingival heights from cleared devices. The subject devices additional gingival heights do not impact the safety or efficacy of the device; these additional heights

				enable use of the healing abutments at more gingival heights.
Total Length (mm)	8.4 - 11.4	3.0~7.0	9.0~11.5	Similar – The subject devices additional lengths fall within the predicate device ranges.
Similarities	*The device has the same material, sterilization method, connection type, indications for use, and principle of operation.*			
Differences	*The device has different fixture body diameters and gingival heights. These differences do not impact the safety or efficacy of the devices.*			

Table 4: Comparison of the Subject and Primary Predicate for Samwon General Abutment Screw

	Subject Device: Samwon General abutment for use with the HEXIM Implant System	**Predicate Device:** S-Plant Dental Implant System **(**K221866)	**Comparison**
Device Name	Samwon General Abutment Screw	Abutment screw for S-Plant Dental Implant System	N/A
Manufacturer	Samwon	IDIS Co, Ltd.	N/A
Classification Name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Same
Product Code	NHA	NHA	Same
Device Class	II	II	Same

OTC or Rx	Rx	Rx	Same
Indications for use	Couple Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	Same
Principle of Operation	As an intermediary connecting the fixation device with Couple Abutment the screw thread is a standard M2.0 screw	Abutment Screw is used to connect an abutment to the fixture	Same
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Same
Surface Treatment	None	None	Same
Sterilization	End User (Steam)	Not Specified	Same
Connection Type	Threaded (M2xP0.4)	Threaded	Same

Diameter	Ø 2.32mm	Ø 2.25, 2.5mm	Different – The subject device diameter is within the range of the predicates and is viewed as equivalent.
Length	10.7mm	9.0, 10.2mm	Different – The subject device length is near the length of the S-Plant (K221866) device. An additional 0.5mm of length does not affect the safety and efficacy of the product.
Similarities	The device has the same material, sterilization method, connection type, indications for use, and principle of operation.		
Differences	The diameter of the subject device differs from the predicate but is within the range of the predicate's diameters. The length of the screw is longer in the predicate device. This additional length does not impact the safety or efficacy of the device. Additionally, mechanical testing of the subject device demonstrated the suitability of the design.		

Table 5: Comparison of the Subject and Primary Predicate for Samwon General Abutment Hex-type Couple Abutment

	Subject Device: Samwon General abutment for use with the HEXIM Implant	**Predicate Device** S-Plant Dental Implant System (K221866)	**Comparison**
Device Name	Hex-type Couple Abutment for the Samwon General abutment for use with the HEXIM Implant System	Dual Abutment for the S-Plant Dental Implant System	N/A
Manufacturer	Samwon	IDIS Co, Ltd	N/A

Classification Name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Same
Product Code	NHA	NHA	Same
Device Class	II	II	Same
OTC or Rx	Rx	Rx	Same
Indication for use	Couple Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.	Same
Principle of Operation	It can be used with an internal Hex fixture (Fixture) with a contracting part of 3.33mm and an internal angle of 11 degrees (included angle). Connection with the fixture is	Using making for general cement-type Prosthesis	Similar – These abutments support tooth prothesis and are affixed to an endosseous implant with a screw.

	made using an Abutment Screw.		
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Same
Surface Treatment	None	None	Same
Sterilization	End User (Steam)	End User (Steam)	Same
Connection Type	Internal Hex	Tapered conical Hex	Similar - The subject device and K221866 have the same connection type.
Body Diameter (mm)	Ø4.5, Ø4.8, Ø5.0, Ø5.5, Ø6.5	Ø3.4, Ø3.6, Ø3.8, Ø4.2, Ø5.2, Ø7.0	Different- The subject device's range of diameters is within the S-Plant predicates range.
G/H (mm)	0.9,1.9,2.9,3.9	1,2,3,4,5	Different – The Gingival height of the subject device is within the range of the predicate devices.
Post Height (mm)	4.0	4,5.5,7	Similar – Both predicate devices have 4mm post heights.
Similarities	The subject device has similar material, sterilization method, connection type, indications for use, and principle of operation. Both are supplied non-sterile.		
Differences	The Subject and predicate devices do have different diameters, but the subject device's diameters are within the range of the predicates, so there is no risk to the safety or efficacy of the product. The subject device has different G/H measurements, but these differences do not affect the safety or efficacy of the device.		

V. STERILIZATION AND SHELF-LIFE TESTING

Sterilization Validation testing for the HEXIM implants (fixtures) has been performed in accordance with:

- ISO 11137:2006 *Sterilization of health care products*
- ISO 11137-1:2006/Amd.2:2018 *Sterilization of health care products -Requirements for validation and routine control - Radiation - Part One: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 11137-2:2019 *Sterilization of health care products - Radiation - Part 2 : Establishing the sterilization dose for gamma sterilization for gamma sterilization.*
- Shelf life was established via accelerated aging per ASTM F 1980-2021 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* at 5 years.
- *LAL bacterial endotoxin testing per USP 41 <85>, rev. 05/2018, USP 41 <161>, rev. 05/2018, ANSI/AAMI ST72:2011. This testing recurs with each batch of implants during production.*

Steam Sterilization validation for non-sterile devices (abutments) has been performed in accordance with:

- ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- ISO 17665-1:2006 *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 17665-2:2009 *Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1*

The Samwon general abutments are supplied non-sterile with no stated shelf life.

VI. BIOCOMPATIBILITY

Biocompatibility has been conducted in accordance with the special controls document, *Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*.

Table 6: Materials of the Proposed Device

Device Part	Material
HEXIM Implant	CP Ti Gr 4 ASTM F67
Samwon General Abutments	Ti 6Al-4V ELI ASTM F136

HEXIM Implant

Biocompatibility testing was conducted on representative final manufactured samples in accordance with:

- ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Testing was performed according to ISO 10993-18, ISO 10993-5 *Tests for in vitro cytotoxicity,*
- ISO 10993-18:2020 *Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process*
- ISO 10993-5:2009 *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-6:2016 *Biological evaluation of medical devices Part 6: Tests for local effects after implantation*
- ISO 10993-10:2021 *Biological evaluation of medical devices Part 10: Tests for skin sensitization*
- ISO 10993-11:2017 *Biological evaluation of medical devices Part 11: Tests for systemic toxicity*
- ISO 10993-23:2021 ISO 10993-23:2021 *Biological evaluation of medical devices Part 23: Tests for irritation*

Samwon General Abutments

Biocompatibility testing was conducted on representative final manufactured samples in accordance with:

- ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.
- ISO 10993-18:2020 *Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process*
- ISO 10993-5:2009 *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-6:2016 *Biological evaluation of medical devices Part 6: Tests for local effects after implantation*
- ISO 10993-10:2021 *Biological evaluation of medical devices Part 10: Tests for skin sensitization*
- ISO 10993-11:2017 *Biological evaluation of medical devices Part 11: Tests for systemic toxicity*

VII. PERFORMANCE TESTING

Bench

Non-clinical validation testing was performed to demonstrate the safety and effectiveness of the device in accordance with the guidelines outlined in the FDA document "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.". The following tests were performed:

- *Fatigue Testing was performed according to ISO 14801:2007 using worst case geometries.*
- *Implant to abutment compatibility was determined through mechanical testing.*
- *A chemical and visual analysis of the HEXIM Implant's SLA blasted surface was performed to demonstrate no blasting particles or cleaning chemicals remain on the surface of the implant.*
- *LAL bacterial endotoxin testing per USP 41 <85>, rev. 05/2018, USP 41 <161>, rev. 05/2018, ANSI/AAMI ST72:2011. This testing recurs with each batch of implants during production.*

The results of these comprehensive tests have met the criteria set by industry standards, establishing substantial equivalence with the predicate device.

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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.

Animal

No animal or clinical testing was performed in support of this submission.

Clinical

No animal or clinical testing was performed in support of this submission.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

The HEXIM implant with Samwon General Abutments constitutes a substantially equivalent medical device. Both the implant and the abutments are similar to the predicate device in terms of design, dimension, material, surface treatment, intended use and technological characteristics. The differences identified in this analysis and listed below do not constitute substantial equivalence concerns.

The subject HEXIM implants have different diameters and lengths than the predicate device (K111889). The subject diameters and lengths fall within the range of the predicate device (K111889), so they do not constitute a substantial equivalence concern.

The subject Cover Screw's body diameter is 3.35mm while the predicate's (K221866) is 3.6mm. This smaller diameter does not constitute a substantial equivalence concern.

The subject Healing Abutment has different diameters and G/H measurements than the predicate device (K221866) and reference device (K222792). The subject device's diameters are within the range of the predicate's (K221866) and have been mechanically tested according to the special controls document, Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance for Industry and FDA Staff, so there is no risk to the safety or efficacy of the product. The subject device's G/H measurements are within the range of the a legally marketed device, reference device (K222792), so the difference does not constitute a substantial equivalence concern

The subject Abutment Screw and the predicate (K221866) device have different diameters and lengths. These differences do not impact the safety and efficacy of the product because the subject device's dimensions are compatible with the subject device's couple abutments and because the device has been mechanically tested according to special controls document Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance for Industry and FDA Staff therefore the difference does not constitute a substantial equivalence concern.

The subject Hex Style Couple Abutment does have different diameters and G/H measurements than the predicate (K221866). The subject device's diameters are within the range of the predicate's, so it does not constitute a substantial equivalence concern. The difference between the subject device and predicates G/H have similar ranges with the subject device's length being 0.1mm smaller than the predicate's. This difference in length is insignificant with respect to the function of the device and does not constitute a substantial equivalence concern.