June 8, 2023

SNUCONE Co., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#303, 142 Gasan digital 1-ro
Geumcheon-gu, Seoul 08507
REPUBLIC OF KOREA

Re: K222792
Trade/Device Name: SNUCONE Tissue Level Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 8, 2023
Received: May 8, 2023

Dear Sanglok Lee:

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

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

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

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

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

Sincerely,

Andrew I. Steen -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222792

Device Name

SNUC●NE Tissue Level Implant System

Indications for Use *(Describe)*

SNUC●NE Tissue Level 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, 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.

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

The assigned 510(k) Number: K222792

01. Date Prepared: May 29, 2023

02. Applicant

Company name: SNUCONE Co., LTD.
Address: 5, Seongseo-ro 75-gil, Dalseo-gu, Daegu, Korea
TEL: 82.53.592.7525
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Email: snucone@naver.com

03. Submission Correspondent

Sanglok, Lee
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04. Proposed Device Identification

Trade Name: SNUCONE Tissue Level Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Primary Product Code: DZE
Secondary Product Code: NHA
Panel: Dental
Regulation Number: 21 CFR 872.3640
Device Class: Class II

05. Indication for use

SNUCONE Tissue Level 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, 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.

06. Predicate and Reference Devices

Primary Predicate
- K181137, IT-III active System manufactured by NEOBIOTECH CO., LTD

Reference Devices
- K141159, K3Pro Konus Dental Implant System, Argon Med. Productions & Vertriebs Gesellschaft mbh & Co. KG
- K121585, TS Implant System by Osstem Implant Co., Ltd.
- K181138, IS-III active System manufactured by NEOBIOTECH CO., LTD
- K200189, Luna Dental Implant System-Healing Abutment, Shinhung MST CO., LTD
- K120043, CSM Internal-R Implant System, CSM Implant
- K201700, BEGO Semados® RS/RSX Implant System by BEGO Implant Systems GmbH & Co. KG
- K190637, Fit & Brilliant Dental Implant System, F&B Technology CO., LTD
- K210161, Any One Onestage Implant System by MegaGen Implant Co., Ltd.

07. Device Description

SNUCONE Implant System Fixture, also known as an endosseous implant, is surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as a crown, bridge, denture. Snucone's abutment and prosthetic components and tools are compatible with the Snucone's fixture only.

1) Fixtures and Cover Screw

There is 1 type of fixture, and the dimensions and specification are as following:

Product	EF	Cover Screw
Picture		
Diameter	Ø3.7, Ø3.8, Ø4.1, Ø4.3, Ø4.8, Ø5.3, Ø5.5, Ø5.8	Ø5.5 / Ø6.7
Length	Ø3.7: 7,8,9,10,11,12,13,14㎜ Ø3.8: 7,8,9,10,11,12,13,14㎜ Ø4.1: 7,8,9,10,11,12,13,14㎜ Ø4.3: 7,8,9,10,11,12,13,14㎜ Ø4.8: 7,8,9,10,11,12,13,14㎜ Ø5.3: 7,8,9,10,11,12,13,14㎜ Ø5.5: 7,8,9,10,11,12,13,14㎜ Ø5.8: 7,8,9,10,11,12,13,14㎜	8㎜
Surface Treatment	Acid etching	Anodizing
Connection	Internal Octa	N/A
Material	Titanium Gr4 (ASTM F67)	Ti 6Al-4V ELI (ASTM F136)
Sterilization	Gamma irradiation	Gamma irradiation
Shelf Life	5 years	5 years

Tolerance of dimension shall be within ± 1% range.

2) Abutment and Component

2-1) Abutment

Dimensions and features of abutment are as following:

Tolerance of dimension shall be within ± 1% range.

Abutment	Solid Abutment	InOcta Closing Screw	InOcta Healing Abutment	InOcta Abutment
Picture				
Use	This device is a one-piece abutment that is secured to the Fixture without other component.	This device is connected to the Fixture and is used during healing period.	This device is used to connect with Fixture to help gum tissue around the implant site heal faster.	This device is a two-piece abutment that is secured to the Fixture with an abutment screw.
Principle of	This product is a	This device is used for	This product is healing	This product is a

Operation	superstructure which is connects with the fixture. It is a one-body type Abutment of screw-retained that does not require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.	protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, This product is removed.	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.	superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental abutment.
Diameter	Ø3.5, Ø4.3	Ø3.5	Ø5.5, Ø6.1, Ø6.3	Ø4.8, Ø5.2, Ø6.2
Total Length	9.5~13.0㎜	5.9㎜	9.0~11.5㎜	6.0~13.0㎜
Gingival Height	-	-	4.0~6.5㎜	0.0~4.0㎜
Post Height	4.0~7.0㎜	-	-	4.0~7.0㎜
Angle(°)	N/A	N/A	N/A	N/A
Anodizing	N/A	Yellow	Yellow	N/A
Prosthetic retention	Cement-retained	-	-	Cement-retained
Restoration	Single-unit Multi-unit	-	-	Single-unit Multi-unit
Material	Ti 6Al-4V ELI (ASTM F136)	Ti 6Al-4V ELI (ASTM F136)	Ti 6Al-4V ELI (ASTM F136)	Ti 6Al-4V ELI (ASTM F136)
Sterilization	End user sterilized	End user sterilized	End user sterilized	End user sterilized
Shelf Life	N/A	N/A	N/A	N/A
Abutment	InOcta Angled Abutment	InOcta Temporary Abutment	Platform Switching Abutment	-
Picture				-
Use	This device is a two-piece abutment that is secured to the Fixture with an abutment screw.	This device is a two-piece abutment that is temporarily fixed to the Fixture with an abutment screw. This device is intended to be used for a maximum timeframe of 6 months.	This device is a one-piece abutment that is secured to the Fixture without other component.	-
Principle of Operation	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental abutment.	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental abutment.	
Diameter	Ø3.8	Ø5.2	Ø4.5, Ø5.5, Ø6.5	-
Total Length	9.5㎜	12.5~14.5㎜	9.9~16.9㎜	-
Gingival Height	-	1.0~3.0㎜	0.0~5.5㎜	
Post Height	7.0㎜	9.5㎜	5.5㎜	
Angle(°)	15° 25°	N/A	N/A	-
Anodizing	N/A	N/A	N/A	-
Prosthetic retention	Cement-retained	Cement-retained	Cement-retained	-
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	-
Material	Ti 6Al-4V ELI (ASTM F136)	Ti 6Al-4V ELI (ASTM F136)	Ti 6Al-4V ELI (ASTM F136)	-
Sterilization	End user sterilized	End user sterilized	End user sterilized	-

Shelf Life	N/A	N/A	N/A	-

2-2) Abutment Screw

Dimensions and features of component are as following:

Abutment Screw	InOcta Abutment Screw
Picture	
Use	This product is a screw used to connect both two-piece Abutment to the Fixture
Principle of Operation	This product is a screw for connected with Abutment and fixture.
Size	D : Ø2.5 / L : 4.5~8.0㎜
Material	Ti 6Al-4V ELI (ASTM F136)
Sterilization	End user sterilized

Tolerance of dimension for InOcta Abutment screw shall be within ± 1% range.

Fixture is packaged with Cover Screw, Abutment is packaged with single-packing or components, in some cases.

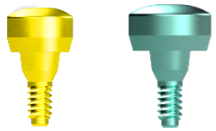
08. Substantial Equivalence Comparison

1) Fixture

	Subject Device	Primary Predicate	Reference Device
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd	Argon Med Productions&Vertriebs Gesellschaft mbH&Co.KG
Device Name	EF Fixture for SNUCONE Tissue Level Implant System	IT-III active System	K3Pro Konus Dental Implant
510(k) Number	Not Assigned Yet.	K181137	K141159
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE
Regulation Number	872.3640	872.3640	872.3640
Indications for Use	SNUCONE Tissue Level 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, 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.	The IT-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, or overdenture restorations and terminal or intermediate Abutment support for fixed bridge work. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal loading.	The Konus K3Pro and K3Pro Rapid Implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
Material	Titanium Gr4 (ASTM F67)	Pure Titanium of ASTM F67	Pure Titanium Grade 4
Design			
Connection	Internal Octa	Internal Octa	Internal Hex
Diameters(⌀)	Ø3.7, Ø3.8, Ø4.1, Ø4.3, Ø4.8, Ø5.3, Ø5.5, Ø5.8	3.5/4.0/4.5/5.0/5.5/6.0/7.0	3.0-6.0mm
Lengths(mm)	Ø3.7: 7,8,9,10,11,12,13,14㎜ Ø3.8: 7,8,9,10,11,12,13,14㎜ Ø4.1: 7,8,9,10,11,12,13,14㎜ Ø4.3: 7,8,9,10,11,12,13,14㎜ Ø4.8: 7,8,9,10,11,12,13,14㎜	7.0/8.5/10.0/11.5/13.0/15.0	7.5-17mm

	Ø5.3: 7,8,9,10,11,12,13,14㎜ Ø5.5: 7,8,9,10,11,12,13,14㎜ Ø5.8: 7,8,9,10,11,12,13,14㎜		
Surface Treatment	Acid etching	SLA	Acid etching
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	Unknown
Similarities	SNUCONE Tissue Level Fixture has the same device characteristics with the primary predicate such as Indication for use, material, design, connection, diameter, length, sterilization method, and principle of operation. The surface treatment is applied to the threaded part only of the subject device and primary predicate. The upper portion of EF Fixture is pure titanium without surface treatment		
Differences	The difference between the subject device and the Predicate device are surface treatment. The surface treatment method of the subject fixture is Acid etching, while the primary predicate is SLA. To support this inconsistency, K141159 is added as a reference device to support the difference in surface treatment method.		

1-2) Cover Screw

	Subject Device	Primary Predicate	Reference Device
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd	Osstem Implant Co., Ltd.
Device Name	Cover screw for SNUCONE Tissue Level Implant System	IT-III active System	TS Implant System
510(k) Number	Not Assigned Yet.	K181137	K121585
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design			
Diameters(⌀)	Yellow: Ø5.5 Sky blue: Ø6.7	5.5/6.9	4.0/4.5/5.0/6.0/7.0
Height (mm)	3.0㎜	Cuff Length: 6.0	Height: 0.4, 1.4, 2.0
Anodizing	Anodizing	Non-Anodizing	Anodizing
Sterilization	Gamma irradiation	Gamma Sterilization	-
Principle of Operation	This product connects with the Dental Implant Fixture to protect the inside of the fixture during bone fusion period after installation of Dental Implant Fixture, and removes the cover screw before inserting the Abutment.	Cover screw as a set of medical devices is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed.	Cover screw as a set of medical devices is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed.
Similarities	The subject and primary predicate devices have the same material, design, principle of operation, and similar diameter.		
Differences	There is a slightly different surface treatment between the subject device and primary predicate. To support this inconsistency, K121585 is added as a reference device to support the difference in surface treatment method.		

2) Abutment, Abutment Screw and Component

2-1) Solid Abutment

	Subject Device	Primary Predicate
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd
Device Name	Solid Abutment for SNUCONE Tissue Level Implant System	IT-III active System
510(k) Number	Not Assigned Yet.	K181137
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(⌀)	Ø3.5, Ø4.3	3.5/4.3
Post Heights (mm)	4.0~7.0㎜	4.0/5.5/7.0
Anodizing	Non-Anodizing	Anodizing / Non-Anodizing
Sterilization	End user sterilized	End user sterilized
Principle of Operation	This product is a superstructure which is connects with the fixture. It is a one-body type Abutment of screw-retained that does not require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.	This product is a superstructure which is connects with the fixture. It is a one-body type Abutment of screw-retained that does not require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.
Similarities	The subject and primary predicate devices have the same material, design, diameter, principle of operation and similar post height.	

2-2) InOcta Closing Screw

	Subject Device	Reference Device
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd
Device Name	InOcta Closing Screw for SNUCONE Tissue Level Implant System	IS-III active System
510(k) Number	Not Assigned Yet.	K181138
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(⌀)	Ø3.5	3.45/3.6
Lengths(mm)	5.9㎜	5.85/6.85/7.45/ 6.4/7.4/8.0
Anodizing	Anodizing	Anodizing/ Non-Anodizing,

Sterilization	End user sterilized	Gamma irradiation
Principle of Operation	This device is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, This product is removed.	It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed.
Similarities	The subject device and reference devices have the same material, design, surface treatment, principle of operation and similar diameter and length.	

2-3) InOcta Healing Abutment

	Subject Device	Primary Predicate	Reference Device
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd	SHINHUNG MST Co., Ltd.
Device Name	InOcta Healing Abutment for SNUCONE Tissue Level Implant System	IT-III active System	Luna Dental Implant System – Healing Abutment
510(k) Number	Not Assigned Yet.	K181137	K200189
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-Gr4
Design			
Diameters(⌀)	Ø5.5, Ø6.1, Ø6.3	5.8/6.3/7.1/7.2	4.3, 4.8, 5.8, 6.3
Gingival Heights(mm)	4.0~6.5㎜	1.5/2.5/3.5/4.5/5.5/6.5	Lengths: 9.2, 10, 10.2, 11, 11.2, 12, 12.2, 13, 13.2, 14
Anodizing	Anodizing	N/A	Anodizing
Principle of Operation	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.	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.	Unknown
Sterilization	End user sterilized	Gamma Sterilization	Unknown
Similarities	The subject and primary predicate devices have the same material, design, principle of operation and similar diameter, gingival height.		
Differences	The diameter of the subject device includes Ø5.5 that is slightly smaller than the primary predicate. To support this inconsistency, K200189 is added as a reference device to support the difference in diameter.		

2-4) InOcta Abutment

	Subject Device	Primary Predicate
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd
Device Name	InOcta Abutment for SNUCONE Tissue Level Implant System	IT-III active System
510(k) Number	Not Assigned Yet.	K181137
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136

Design					
	Octa	Non-Octa	Octa	Non-Octa	SCRP
Diameters(⌀)	Ø4.8, Ø5.2, Ø6.2		4.3/4.85/5.5/6.55		
Gingival Heights(mm)	0.0~4.0㎜		0/1/2/3/4		
Anodizing	Non-Anodizing		TiN-Coating		
Principle of Operation	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental abutment.		This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.		
Sterilization	End user sterilized		End user sterilized		
Similarities	The subject and primary predicate devices have the same material, design, principle of operation, gingival height, and similar diameter				

2-5) InOcta Angled Abutment

	Subject Device	Primary Predicate	
Company	SNUCONE Co., LTD.	Neobiotech Co., Ltd	
Device Name	InOcta Angled Abutment for SNUCONE Tissue Level Implant System	IT-III active System	
510(k) Number	Not Assigned Yet.	K181137	
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	
Design			
	Octa	Octa	Non-Octa
Diameters(⌀)	Ø3.8	3.7/4.3	
Lengths(mm)	9.5㎜	9.5/9.68	
Angle(°)	15° 25°	15° 25°	
Anodizing	Non-Anodizing	Non-Anodizing	
Principle of Operation	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.	
Sterilization	End user sterilized	End user sterilized	

Similarities	The subject and primary predicate devices have the same material, design, angle, surface treatment, principle of operation, and similar diameter, length.

2-6) InOcta Temporary Abutment

	Subject Device	Reference Device	
Company	SNUCONE Co., LTD.	CSM Implant	BEGO Implant Systems GmbH & Co. KG
Device Name	InOcta Temporary Abutment for SNUCONE Tissue Level Implant System	CSM Internal-R Implant System	PS TTiA and PS TTiA NH
510(k) Number	Not Assigned Yet.	K120043	K201700
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Design			
Diameters(⌀)	Ø5.2	4.5㎜, 5.5㎜	3.2, 3.7, 4.1, 5.1㎜
Lengths(mm)	12.5~14.5㎜	12.8㎜, 13.3㎜, 13.8㎜, 14.8㎜, 15.8㎜, 16.8㎜	Overall height: 12㎜
Anodizing	Non-Anodizing	N/A	N/A
Principle of Operation	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.	Abutment fastened to fixture for working model with torx driver	Unknown
Maximum timeframe for use	≤ 6 month	Unknown	≤ 6 month
Sterilization	End user sterilized	End user sterilized	End user sterilized
Similarities	The subject and reference device (K120043) have the same material, design, angle, surface treatment, principle of operation, and similar diameter, length. The subject and reference device (K201700) have the same maximum timeframe for use.		

2-7) Platform Switching Abutment

	Subject Device	Reference Device
Company	SNUCONE Co., LTD.	F&B Technology Co., Ltd.
Device Name	Platform Switching Abutment for SNUCONE Tissue Level Implant System	Solid Abutment for Fit & Brilliant Dental Implant System
510(k) Number	Not Assigned Yet.	K190637
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136

Design		
Diameters(⌀)	Ø4.5, Ø5.5, Ø6.5	Ø4.0 Ø4.5 Ø5.0 Ø5.5 Ø6.0 Ø6.5
Post Heights(mm)	5.5㎜	4, 5.5, 7㎜
Sterilization	End user sterilized	Steam Sterilization by user
Similarities	The subject and primary predicate devices have the same material, design, diameter, and lengths.	

2-8) Abutment Screw

	Subject Device	Reference Device	
Company	SNUCONE Co., LTD.	MegaGen Implant Co., Ltd.	
Device Name	Abutment Screw	Multi Post Screw For AnyOne Onestage Implant System	Abutment Screw For AnyOne Onestage Implant System
510(k) Number	Not Assigned Yet.	K210161	
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Design			
Diameters(⌀)	Ø2.5	2.5	2.5, 2.6
Lengths(mm)	4.5~8.0㎜	8.1	4.85, 5.5
Principle of Operation	This product is a screw for connected with Abutment and fixture.	The Multi Post Screw is used for connecting the Multi Post, EZ Post Abutment, Gold Abutment and CCM Abutment to the Fixture	The Abutment Screw is used for connecting the Angled Abutment to the Fixture, and Healing Cap, Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, CCM Cylinder to the Octa Abutment.
Sterilization	End user sterilized	Non-sterile	Non-sterile
Similarities	The subject and reference device have the same material, design, diameter, principle of operation and similar diameter.		

09. Non-Clinical Test

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- **Mechanical Performance**
  - Fatigue testing for worst-case implant body EF1.8-3714S with 25° InOcta Angled Abutment was conducted according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” and “ISO 14801:2016 Dentistry - Fatigue test for endosseous dental implants” under the worst case scenario.
  - SEM/EDS analysis for worst-case implant body was conducted to confirm removal of the surface treatment media according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implant Abutment.”.
- **Sterilization, Shelf-life and Packaging for Sterile Product**
  - End User Sterilization Validation according to ISO 17665-1:2006, ISO 17665-2:2009, ISO 11737-1:2006, and ISO 11737-2:2009
  - Gamma sterilization validation according to ISO 11737-1, and ISO 11737-2
  - Accelerating aging test according to ASTM F1980-16, ASTM D882-12, ASTM F1140-13, ASTM F1929-15, and ASTM F2096-11
- **MR Environment Condition**

  Non-clinical worst-case MRI review was performed to evaluate the metallic SNUCONE Tissue Level Implant System devices in the MRI environment using scientific rationale and published literature (e.g., 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 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.
- **Bacterial Endotoxin**
  - ANSI/AAMI ST72:2019 Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
- **Biocompatibility**

  Subject device has been evaluated for biocompatibility according to ISO 10993

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device

10. Conclusion

SNUCONE Tissue Level Implant System constitutes a substantially equivalent medical device. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, SNUCONE Tissue Level Implant System and its predicates are substantially equivalent.