Sewon Medix Inc.
Jinsoo Lee
CEO
#29, Sa-sang-ro, 375beon-gil, Sa-sang-gu
Sa-sang-gu, Busan 46700
Korea, South

7/7/2023

Re: K222707
Trade/Device Name: IH Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 01, 2023
Received: June 08, 2023

Dear Jinsoo 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222707

Device Name
IH Implant System

Indications for Use *(Describe)*
IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date: July 7, 2023
K222707

1. Submitter

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2. Device Information

- Trade Name: IH Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous dental implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II

3. Predicate Device

Primary Predicate Device

IH Implant System, SEWONMEDIX Inc., K153521

Reference Devices

HIOSSEN Implant System, HIOSSEN Inc., K140934
OSSTEM Implant System-Abutment, OSSTEM Implant Co., Ltd., K161689
Multi Angled Abutment, OSSTEM Implant Co., Ltd. K123755

4. General Description

4-1) IH2 SLA Fixture

IH2 SLA Fixtures are endosseous threaded implants available in diameters of 3.7, 4.2, 4.6, 5.1 and 5.95mm. IH2 SLA Fixture is dental implant fixture that is used to replace root part of the tooth on full or partial edentulous patients. The surface treatment was carried out by sand blasting with alumina (Al2O3) powder followed by acid etching on the surface of machined titanium in order to provide roughness on the surface that would increase the surface area for the bone contact. The implants are compatible with SEWONMEDIX restorative components featuring the internal conical connection.

< Table a: Identification of subject device and primary predicate device >

Platform	Fixture Diameter	Height(mm)					
		7	8.5	10	11.5	13	15
Mini	Ø3.7	-	○	○	○	○	○
Regular	Ø3.8	●	○	○	○	○	○
	Ø4.2	●	○	○	○	○	○
	Ø4.5	●	○	○	○	○	○
	Ø5.0	●	○	○	○	○	○
	Ø5.95	●	●	●	●	●	-

(●: Subject Device / ○: primary predicate device)

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4-2) IH Healing Abutment

IH Healing Abutments is premanufactured dental implant abutments which can be directly connected to the endosseous dental implant to support healing of the surrounding soft tissue. The following table summarizes the matching of various healing abutments and Abutment Gingival height, including key information of each type of IH Healing Abutment according to the connection type.

< Table b: Identification of subject device and primary predicate device >

Diameter	Height(mm)								
	6.5	7.5	8.4	8.5	9.5	10.4	10.5	11.5	12.4
Ø4	●	○	○	●	○	○	●	○	○
Ø4.5	●	○	○	●	○	○	●	○	○
Ø5	●	○	○	●	○	○	●	○	○
Ø5.5	●	○	○	●	○	○	●	○	○
Ø6	●	○	○	●	○	○	●	○	○
Ø6.5	●	○	○	●	○	○	●	○	○
Ø9	●	●	●	●	●	●	●	●	●

(●: Subject Device / ○: primary predicate device)

4-3) IH Cement Abutment

A Premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Cement retained restoration: IH Cement Abutment
IH Prosthetic System is device made of titanium, titanium alloy intended for use as an aid in prosthetic restoration. Its surfaces are partially TiN-Coated or uncoated.

< Table c: Identification of subject device and primary predicate device >

Platform	Diameter	Height(mm)		
		4	5.5	7
Mini	Ø4.5	-	○	●
Regular	Ø4.5	●	○	●
	Ø5	○	○	○
	Ø5.5	○	○	○
	Ø6	○	○	○
	Ø6.5	○	○	○

(●: Subject Device / ○: primary predicate device)

4-4) IH Multi-unit Abutment

A pre-manufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
The IH Multi-unit Abutment is made of titanium alloy.

< Table d: Identification of subject device and primary predicate device >

- Straight type

Connect Diameter	Gingival Height(mm)			
	1.5	2.5	3.5	4.5
Ø 2.88	●	●	●	●
Ø 3.43	○	○	○	○

- Angled type

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Connect Diameter	Angle(°)	Gingival Height(mm)					
		2.5	3	3.5	4	4.5	5
Ø 2.88	17	●	●	-	●	-	-
	30	-	-	●	●	-	●
Ø 3.43	17	○	●	○	●		-
	30	-	-	○	●	○	●

(●: Subject Device / ○: primary predicate device)

5. Indications for Use

IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

6. Substantial Equivalence

- **Substantial Equivalence (Fixture System)**

Item	**Subject device**	**Primary predicate device**	**Reference device**
Device name	**IH2 SLA Fixture**	**IH2 SLA Fixture**	**ET III SA Fixture / ET III SA Ultra Wide Fixture / ET II SA Fixture**
510(k) No.	N/A	K153521	K140934
Design			
Indication for Use	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	The HIOSSEN 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. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.
Surgery Type	One or two stage Surgery	One or two stage Surgery	One or two stage Surgery
Structure	- Internal Hex connected - Submerged fixture - Tapered body shape - Cutting edge with self-tapping - 0.8mm thread pitch	- Internal Hex connected - Submerged fixture - Tapered body shape - Cutting edge with self-tapping - 0.8mm thread pitch	- Internal Hex connected - Submerged fixture - Tapered body shape & straight body shape
Diameter (D)	3.7, 4.2, 4.6, 5.1, 5.95	3.7, 4.2, 4.6, 5.1	3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.25, 4.63, 4.65, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8
Length (mm)	7.0, 8.5, 10, 11.5, 13, 15	8.5, 10, 11.5, 13, 15	6.2, 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)

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Surface	SLA	SLA	SLA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	5 years	5 years	8 years

As previously cleared in K153521 except with added new models of diameter 5.95 or length 7.0, new packaging types (IH2 Fixture with Pre-Mount type). The subject device has the same indications for use as the primary predicate device (K153521) and there is no difference that would impact substantial equivalence.

Item	**Subject device**	**Primary predicate device**	**Reference device**
Device name	**IH Cover Screw**	**IH Cover Screw**	**Cover Screw**
510(k) No.	N/A	K153521	K140934
Design			
Device Description	Used to protect the exposed platform of the implant during healing period.	Used to protect the exposed platform of the implant during healing period.	Used to protect the exposed platform of the implant during healing period.
Diameter (D)	3.13, 3.6	3.13/3.6	3.03, 3.58, 3.25, 3.4, 3.75, 3.9
Length (mm)	5/5.2/5.8	5/5.8	5.25, 5.9, 6.25, 6.85, 6.9, 7.5
Material	Pure Titanium Gr. 4 (ASTMF67)	Pure Titanium Gr. 4 (ASTMF67)	Pure Titanium (ASTM F 67)
Surface	Anodizing	Anodizing	Anodizing

As previously cleared in K153521 except with added new models of length 5.2mm.

- **Substantial Equivalence (IH Prosthetic System)**

Item	**Subject device**	**Primary predicate device**
Device name	**IH Healing Abutment**	**IH Healing Abutment**
510(k) No.	N/A	K153521
Design		
Description	IH Healing Abutment is used to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointergration.	IH Healing Abutment is used to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointergration.
Connection Type	Screw Connected	Screw Connected
Diameter (D)	4/4.5/5/5.5/6/6.5/9	4/4.5/5/5.5/6/6.5
Height(mm)	6.5/7.5/8.4/8.5/9.5/10.4/10.5/11.5/12.4	7.5/8.4/9.5/10.4/11.5/12.4
Material	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Surface	None	None

As previously cleared in K153521 except with added new models of diameter 9 and height 6.5, 8.5, 10.5, 11.5mm.

Item	**Subject device**	**Primary predicate device**

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Device name	**IH Cement Abutment**	**IH Cement Abutment**
510(k) No.	NA	K153521
Design		
Description	A Premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation. Cement retained restoration: IH Cement Abutment IH Prosthetic System is device made of titanium, titanium alloy intended for use as an aid in prosthetic restoration. Its surfaces are partially TiN-Coated or uncoated.	IH Cement Abutment to fabricate a prosthesis of internal single & bridge cement retained type.
Connection Type	External Hex-Connected	External Hex-Connected
Diameter (D)	4.5/5/5.5/6/6.5	4.5/5/5.5/6/6.5
G/H Length (mm)	1/1.5/2/2.5/3/3.5/4/4.5/5	1/1.5/2/2.5/3/3.5/4/4.5/5
Post Length (mm)	4/5.5/7	4/5.5/7
Material	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Surface	Partial TiN coated	Partial TiN coated

As previously cleared in K153521 except with added new models of diameter 4.5 x G/H x 4 and 7 mm.

Item	**Subject device**	**Primary predicate device**	**Reference device**
Device name	**IH Multi-unit Abutment (Straight type)**	**IH Multi-unit Abutment (Straight type)**	**Multi Abutment**
510(k) No.	N/A	K153521	K161689
Design			
Description	A pre-manufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation. The IH Multi-unit Abutment is made of titanium alloy.	IH Multi-Unit Abutment is used for screw retained multiple case.	Multi Abutment is used for edentulous mandible or maxilla to make full denture.
Connection Type	Screw & External Hex-Connected	Screw & External Hex-Connected	Screw & External Hex-Connected
Diameter (D)	4.8	4.8	4.8
Connection Diameter (Ø)	2.88, 3.43	3.43	2.88, 3.43
G/H Length (mm)	1.5/2.5/3.5/ 4.5	1.5/2.5/3.5/ 4.5	1/2/3/4/5

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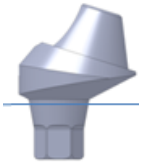
Material	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Surface	None	None	Partial TiN coated

IH Multi-unit Abutment (Straight, Angled) is as previously cleared in K153521 except added New models of angled type of gingival height 3, 4, 5 and Mini type.

Item	**Subject device**	**Primary predicate device**	**Reference device**
Device name	**IH Multi-unit Abutment (Angled type)**	**IH Multi-unit Abutment (Angled type)**	**Multi Angled Abutment**
510(k) No.	N/A	K153521	K123755
Design			
Description	A pre-manufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation. The IH Multi-unit Abutment is made of titanium alloy.	IH Multi-Unit Abutment is used for screw retained multiple case.	The Multi Angled Abutment is device made of titanium alloy intended for use as an aid in prostrhtic restoration.
Connection Type	Screw & External Hex-Connected	Screw & External Hex-Connected	Screw & External Hex-Connected
Diameter (Ø)	4.8	4.8	4.8
Connection Diameter (Ø)	2.88, 3.43	3.43	2.88, 3.43
G/H Length (mm)	2.5/3/3.5/4/4.5/5	2.5/3.5/4.5	2.5/3/3.5/4/4.5/5
Angle(°)	17, 30	17, 30	17, 30
Material	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Surface	None	Partial TiN coated	None

IH Multi-unit Abutment (Straight, Angled) is as previously cleared in K153521 except added New models of angled type of gingival height 3, 4, 5

- **Substantial Equivalence Review:**
  Subject devices in this submission are substantially equivalent to the identified prior clearances.; therefore, manufacturing process including raw material, machining, cleaning and surface treatment and similar design and technological characteristics as the primary predicate device (K153521).

  Refer to the difference of additional products for detail as below table.

Type	Product name	Identity
Fixture System	IH2 SLA Fixture	- It was cleared under K153521 - New models of diameter 5.95 or length 7.0 are added. - New packaging types (IH2 Fixture with Pre-Mount type) is added.
	IH Cover Screw	It was cleared under K153521 except with added new models of length 5.2mm.

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IH Prosthetic System	IH Healing Abutment	- It was cleared under K153521 - New models of diameter 9 and height 6.5, 8.5, 10.5, 11.5mm is added.
	IH Cement Abutment	- It was cleared under K153521 - New model with a diameter of 4.5 x G/H x 4 &7mm is added.
	IH Multi-unit Abutment (Straight, Angled)	- It was cleared under K153521 - New models of angled type of gingival height 3, 4, 5 and Mini type is added.
	IH Multi-unit Abutment Screw	Add length 7.5, 8, 9.1 or diameter 2, 2.05 of existing device

IH Implant System has been subjected to performance and product validations prior to release. The differences between the subject device and predicate devices are detailed shape and detailed dimension of diameter and length.

8 Summary of non-clinical testing

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

- Endotoxin testing on the Subject device or suitable test specimens was performed following USP<85> and USP<161> according to the endotoxin sampling plan
- Biological Evaluation of the Subject device was performed according to ISO 10993-1. Cytotoxicity Testing per ISO 10993-5. Biocompatibility information is also leveraged from primary predicate device(K153521).

• Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
• Gamma sterilization validation Test Report according to ISO 11137-1 and ISO 11137-2
• End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, ISO 11138-1 and ISO 11138-3
• Shelf Life Test according to ASTM F88, ASTM F1140, ASTM F1929, and ASTM F2096, ASTM F1980 and ISO 11607

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate devices. 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.

9 Conclusion

The comparison of similarities and differences between the proposed devices and the respective predicate devices demonstrate that the subject device is substantially equivalent to the identified predicate devices.