DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 14, 2016

Sewon Medix Inc.
% April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K153521
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: September 12, 2016
Received: September 16, 2016

Dear April 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DENTAL IMPLANT SYSTEM
SEWONMEDIX
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Indication for Use Statement

510(k) Number: K 153521

Device Name: IH Implant System

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.

Prescription Use X OR Over-The-Counter Use _____.

(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This summary information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Submitter

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- 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
- Date prepared: 10/05/2016

General Description :

IH2 SLA Fixture is dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The surface is SLA (Sandblasted, Large grit and Acid etched) treated. IH2 SLA Fixture has a various diameters 3.7 to 5.1 mm (3.7, 4.2, 4.6 and 5.1mm) and lengths 8.5 to 15mm (8.5, 10, 11.5, 13 and 15mm).

IH Prosthetic System is device made of titanium, titanium alloy, CCM alloy and POM intended for use as an aid in prosthetic restoration. It consists of Abutments (Healing Abutment, Solid Abutment, Cement Abutment, Angled Abutment, Temporary Abutment, Multi-unit Abutment and FreeMilling Abutment), Solid Protect Cap, Abutment Screws, Healing Cap, Cylinders (CCM Cylinder, Temporary Cylinder, Plastic Cylinder) and Cylinder Screws. Its surfaces are partially TiN coated or uncoated. IH Prosthetic System is supplied non-sterile and should be sterilized before use. It has a various diameters, gingival heights, heights and angles. Healing Abutment has a various diameters 4 to 6.5mm (4, 4.5, and 5, 5.5, 6 and 6.5 mm) and lengths 7.5 to 12.4mm (7.5, 8.4, 9.5, 10.4, 11.5 and 12.4mm). Solid Abutment has various diameters 4 to 7mm (4, 4.5, and 5, 5.5, 6 and 6.5 mm), gingival heights 1 to 5mm (1, 1.5, 2, 2.5, 3, and 3.5, 4, 4.5 and 5 mm) and heights 4 to 7mm (4, 5.5 and 7mm). Cement Abutment has various diameters 4.5 to 6.5mm (4.5, 5, 5.5, 6 and 6.5mm), gingival heights 1 to 5mm (1, 1.5, 2, 2.5, 3, and 3.5, 4, 4.5 and 5 mm) and heights 4 to 7mm (4, 5.5 and 7mm). Angled Abutment has various diameters 4.5 to 6mm (4.5, 5, 5.5 and 6mm), gingival heights 2 to 4mm (2, 3, and 4mm), heights 7.5 to 8mm (7.5 and 8mm) and angle 15° to 25° (15° and 25°), Temporary Abutment has various diameters 4 to 4.5mm (4 and

4.5mm), gingival heights 1 to 3mm (1 and 3mm) and height 9.6mm. Multi-unit Abutment has various diameters 4.7 to 5.13mm (4.7, 4.8 and 5.13mm), gingival heights 1.5 to 4.5mm (1.5, 2.5, 3.5 and 4.5mm) and angle 17° to 30° (17° and 30°) and FreeMilling Abutment has various diameters 4.5 to 6.5mm (4.5, 5, 5.5, 6 and 6.5mm), gingival heights 1 to 3mm (1, 2 and 3mm) and heights 10 to 12mm (10, 11 and 12mm). IH Prosthetic System is device made of titanium, titanium alloy, CCM alloy and POM. Angled Abutment, Temporary Abutment, Healing Cap, Temporary Cylinder and FreeMilling Abutment are made of titanium. Healing Abutment, Solid Abutment, Cement Abutment, Multi-unit Abutment, Abutment Screw and Cylinder Screw are made of titanium alloy. CCM Cylinder is made of Cobalt-Chrome-Molybdenum alloy. Solid Protect Cap and Plastic Cylinder are made of POM.

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.

Predicate Device:

Substantial Equivalence Matrix (IH2 SLA Fixture)

- TS Fixture System, OSSTEM Implant Co., Ltd. K121995 - primary predicate
- Straumann® Bone Level Tapered Implant, Institut Straumann Ag, K140878

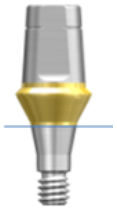
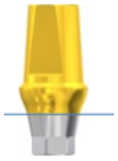
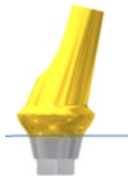
	IH2 SLA Fixture	Predicate devices	
		primary predicate	reference predicate
		TS Fixture System	Straumann® Bone Level Tapered Implant
Manufacturer	Sewon Medix Inc.	OSSTEM Implant Co., Ltd.	Institut Straumann Ag
Design		 **TSIII SA Fixture**	
510(k) No.	K153521	**K121995**	**K140878**
Indication for Use	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	The TS Fixture System is indicated for use in partially or fullly edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw	Straumann® dental implants are indicate for oral endosteal implantation in the upper and low jaw and for the functional and esthetic oral rehabiliation of edentulous and partially

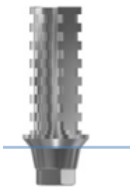
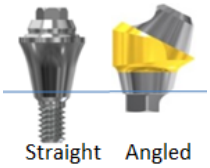
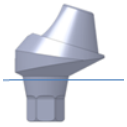
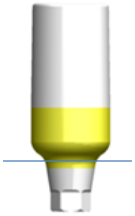
	multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	retained, or overdenture restorations, and final or temporary abutment support for fixed bridge work. It is intended for delayed loading.	dentate patients. Straumann dental implants can also be used for immedicate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridge and partial or full dentures, which are connected to the implants by the correponding elements(abutments). In case of fully edentulous patients, 4 or more implants must be used in immediately loaded case.
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 (TSIII SA Fixture) - Cutting edge with self-tapping - 0.8mm thread pitch	- Internal connected - Submerged fixture - Tapered body shape - Cutting flutes - 0.8mm thread pitch
Connection Type	Internal hex connection	Internal hex connection	Internal connection
Diameter (D)	3.7, 4.2, 4.6, 5.1	TSIII SA Fixture 3.75, 3.77, 4.2, 4.25, 4.6 4.63, 4.65, 5.05, 5.08, 5.1	3.3, 4.1, 4.8
Length (mm)	8.5, 10, 11.5, 13, 15	7, 8.5, 10, 11.5, 13, 15	8, 10, 12, 14, 16
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)
Surface	SLA	SA	SLA

Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	5 years	8 years	-

Substantial Equivalence Matrix (IH Prosthetic System)

- Hiossen Prosthetic System, OSSTEM Implant Co., Ltd., K140507 - primary predicate
- Multi Angled Abutment, OSSTEM Implant Co., Ltd., K123755
- Healing Abutment, OSSTEM Implant Co., Ltd., K081575

	IH Prosthetic System	**Predicate devices**		
		primary predicate	**reference predicate**	
		Hiossen Prosthetic System	**Multi Angled Abutment**	**Healing Abutment**
Manufacturer	Sewon Medix Inc.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Design	 Healing	-	-	 Healing
	 Solid	 Rigid	-	-
	 Cement	 Transfer		-
	 Angled	 Angled	-	-

	 Temporary	 Temporary	-	-
	 Straight Angled Multi-Unit	 Convertible	 Multi Angle	-
	 FreeMilling	 Freeform	-	-
510(k) No.	NA	**K140507**	**K123755**	**K081575**
Description	Healing Abutment is used to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointergration. Angled Abutment is an abutment which has certain angle to easy for adjustment of installation angle of prosthesis. Temporary Abutment is used temporary until final prosthesis is made to maintain esthetic appreciation and chew ability. Multi-Unit Abutment is used for scerew retained multiple case. Solid, Cement and FreeMilling Abutment	The Hiossen Prosthetic System is intended for use an aid in prosthetic restoration. It consists of Abutment, overdenture components and Abutment Screws. The Hiossen Prosthetic system is similar to other commercially available products base on the intended use, the technology used, the claims, the material composition employed and permance characteristics.	Multi Angled Abutment is used to elevate restoration platform when restoration to implant level is not practical due to depth or angle of implant for the edentulous patients in Anterior and Posterior , not customizable and can't be use a single product.	Uesd to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointergrati on.

	to fabricate a prosthesis of internal single & bridge cement retained type.			
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.	Hiossen Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Multi Angled Abutment is intended for use a dental implant to provide support for prosthetic restoration such as crowns, bridges, or overdentures.	HU/HS/HG Prosthetic System is intended for use as an aid presthetic restioration.
Structure	External Hex	External Hex	External Hex	-
Connection Type	Screw & External Hex-Connected	Screw & External Hex-Connected	Screw & External Hex-Connected	Screw Connected
Diameter (D)	Healing : 4.0/4.5/5.0/5.5 /6.0/6.5 Solid : 4.0/4.5/5.0/5.5/ 6.0/6.5/7.0 Cement : 4.5/5.0/5.5 /6.0 /6.5 Angled : 4.5/5.0/5.5 /6.0 Temporary Abutment : 4.0/4.5 Multi-unit Abutment _Straight : 4.8 _Angled : 4.7/5.13 FreeMilling : 4.5/5.0 /5.5/6.0/6.5	Rigid : 4.0/4.6/5.0/6.0 /7.0/8.0 Transfer : 4.0/4.6/5.0/ 6.0/7.0/8.0 Angled : 4.0/4.3/4.5/ 4.8/5.5/6.0 Temporary : 4.0/4.3/ 4.5 Convertible : 3.5/4.0/ 4.8/5.5/6.0 Freeform : 4.0/5.5 /7.0	Multi Angle : -	Healing : 4.0/4.5/5.0//6. 0/7.0/8.0

G/H Length (mm)	Healing : - Solid : 1.0/1.5/2.0/2.5/ 3.0/3.5/4.0/4.5/5.0 Cement :1.0/1.5/2.0/ 2.5 /3.0/3.5/4.0/4.5/5.0 Angled : 2.0/3.0/4.0 Temporary : 1.0/3.0 Multi-unit Abutment _Straight : 1.5/2.5/3.5/ 4.5 _Angled : 2.5/3.5/.5 FreeMilling : 1.0/2.0 /3.0	Rigid : 0.5/1.0/2.0/2.5/ 3.0/4.0/5.0 Transfer : 0.5/1.0/2.0/ 2.5/3.0/4.0/5.0 Angled : 0.5/1.0/2.0 / 2.5 / 3.0 / 4.0 Temporary : 1.0/2.0/ 3.0/4.0 Convertible : 0.5/1.0 /2.0/2.5/3.0/4.0/5.0 /6.0 Freeform : 0.5/1.0 /1.5/2.0/2.5/3.0 /4.0/5.0	Multi Angle : -	Healing : 3.0/4.0/5.0/7.0
Post Length (mm)	Healing : - Solid : 4.0/5.5/7.0 Cement : 4.0/5.5/7.0 Angled : 7.5/8.0 Temporary : - Multi-unit Abutment _Straight : 2.2 _Angled : - FreeMilling : 10.0 /11.0 /12.0	Rigid : 4.0/5.5/7.0 Transfer : 4.0/5.5/7.0 /8.0 Angled : - Temporary : - Convertible : - Freeform :-	Multi Angle : -	Healing : -
Angle(°)	Angled : 15°/25° Multi-unit_Angled : 17°/30°	Angled : 17°	Multi Angel : 17°/30°	-
Material of Abutment	Titanium Alloy (ASTM F 136) : Healing, Solid, Cement, Multi-unit Pure Titanium Gr. 4 (ASTMF67-06) : Angled, Temporary, FreeMilling	Titanium Alloy (ASTM F 136) : Rigid, Transfer, Angled, Convertible, Freeform Pure Titanium Gr. 4 (ASTMF67-06) : Temporary	Titanium Alloy (ASTM F 136) :	Pure Titanium Gr.4 (ASTMF67-06)
Surface	Machine or TiN	Machine or TiN	Machine	Machine
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile	Radiation Sterile

Technological Characteristics	IH Prosthetic System is similar to predicate devices such as shape, structure, dimension and material. but it has different characteristics for each abutment.		
	1.Material		
		IH Prosthetic System	Predicate device
	Healing	Titanium Alloy	Pure Titanium Gr.4
	Angled	Pure Titanium Gr.4	Titanium Alloy
	FreeMilling	Pure Titanium Gr.4	Titanium Alloy
	2.Shape (TiN Coating area)		
		IH Prosthetic System	Predicate device
	Solid / Cement	Gingiva to Post (Half)	Only Gingiva (Middle)

	FreeMilling	Non Coating	Only Gingiva (Middle)
	3.Shape (Post Angle)		
		IH Prosthetic System	Predicate device
	Angled	15° / 25°	17°
	4.Sterilization		
		IH Prosthetic System	Predicate device
	Healing	Non-Sterile	Radiation Sterile
	others	Non-Sterile	Non-Sterile

Substantial Equivalence Review:

IH2 SLA Fixture has same material, machining, surface treatment, and indication for use and similar design and technological characteristics as the predicate device. IH Prosthetic System has same indication for use and manufacturing process including raw material, machining, cleaning and surface treatment and similar design and technological characteristics as the predicate device.

IH Implant System has been subjected to performance and product validations prior to release. Testing including biocompatibility has been performed to ensure the devices comply with the applicable International and US regulations.

The differences between the subject device and predicate devices are detailed shape and detailed dimension of diameter and length.

Any differences between the subject device and predicate devices do not raise new types of substantially equivalent issues.

Summary of non-clinical testing:

		IH Implant System	Predicate Device	Ref.
Biocompatibility (Fixture)	Cytotoxicity	OK	OK	-
	Sensitization	OK	OK	-
	Intracutaneous Reactivity	OK	OK	-
	Acute Systemic	OK	OK	-
	Implantation	OK	OK	-
	Genotoxicity	OK	OK	-
Biocompatibility (Prosthetic)	Cytotoxicity :	OK	OK	-
	Sensitization :	OK	OK	-
	Irritation	OK	OK	-
	Acute Systemic	OK	OK	-
	Genotoxicity	OK	OK	-
Roughness of SLA Surface (Ra)		2.861±0.262 ㎛	2.5~3.0 ㎛	Osstem product Catalog
Sterilization Validation		VDmax 25 SAL 10^{-6}	VDmax 25 SAL 10^{-6}	-
Packaging Validation (Shelf life)		5years	8years	-

Testing including biocompatibility has been performed to demonstrate that the devices comply with the applicable international and US regulations.

Fatigue testing for IH2 SLA Fixture and IH 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 14801:2007 Dentistry - Fatigue test for endosseous dental implants with the worst case scenario. The results are in compliance with it and were similar to previously cleared predicate devices.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act.21 CFR Part 807and based on the information provided in this premarket notification Sewon Medix Inc. Therefore, the IH Implant System is substantially equivalent to the predicate device as described herein.