November 15, 2019

Hiossen, Inc.
Peter Lee
QA/RA Manager
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K191201
Trade/Device Name: EM SA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 14, 2019
Received: November 15, 2019

Dear Peter 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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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Section 5 Indication for Use Statement – 1 PAGE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number (*if known*)
K191201

Device Name
EM SA Implant System

Indications for Use (*Describe*)

The EM SA Implant System (DENTURE) is intended to be place in the bone of the upper or lower jaw arches providing support to dental prosthetic devices, specifically for denture stabilization to restore a patient's chewing function. It is intended for single use only.

The EM SA Implant (NARROW RIDGE) is intended to be use in the treatment of missing mandibular central and lateral incisors to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. 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 807 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K191201

510(k) Summary

(1) Submitter Information:

Submitted by:	Hiossen, Inc. 85 Ben Fairless Drive Fairless Hills, PA 19030
Contact Person:	Peter Lee
Telephone Number:	267-759-7031
Fax Number:	267-759-7031
Date Prepared:	November 15, 2019

(2) Device Name:

• Proprietary Name:	EM SA Implant System
• Classification Name:	Endosseous dental implant
• CFR Number:	872.3640
• Device Class:	Class II
• Product Code:	DZE

(3) Predicate Devices:

	Device	510(k)	Manufacturer
Primary Predicate	MS SA Implant System	K122171	OSSTEM
Reference Device	MS System	K083067/ K072959	OSSTEM
Reference Device	Hiossen Implant System	K140934	HIOSSEN

(4) Description of Device:

The EM SA Implant System is a dental implant made of titanium alloy (Ti-6Al-4V) and is supplied sterile. The surface treatment of EM SA Implant System is SA (Sandblasted and Acid etched) and is intended to be surgically placed in the bone of the upper or lower jaw arches.

The EM SA Implant System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. It is substantially equivalent in design, function and intended use to the OSSTEM Implant Co., Ltd.'s MS SA Implant System (K122171).

Device	Thread Diameter(mm)	Thread Length(mm)
EM SA Implant System (Denture)	∅2.0, ∅2.5, ∅3.0	8.5, 10.0, 11.5, 13.0, 15.0
EM SA Implant System (Narrow Ridge)	∅2.5, ∅3.0	8.5, 10.0, 11.5, 13.0, 15.0

(5) Indication For Use:

The EM SA Implant System (DENTURE) is intended to be place in the bone of the upper or lower jaw arches providing support to dental prosthetic devices, specifically for denture stabilization to restore a patient's chewing function. It is intended for single use only.

The EM SA Implant (NARROW RIDGE) is intended to be use in the treatment of missing mandibular central and lateral incisors to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. It is intended for delayed loading.

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(6) Substantial Equivalence:

HIOSSEN believes the EM SA Implant System is substantially equivalent to the primary predicate device, OSSTEM MS SA Implant System in November 2012 (510(k) number K122171).

Device	Proposed Device EM SA Implant System (Denture)	Primary Predicate MS SA System (Denture)	Reference Device MS System	Reference Device HIOSSEN IMPLANT SYSTEM
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.	Osstem Co., Ltd.	Hiossen, Inc.
510(K) No.	New device	K122171	K083067/K072959	K140934
Design				
Intended use	The EM SA Implant System (DENTURE) is intended to be place in the bone of the upper or lower jaw arches providing support to dental prosthetic devices, more specifically denture stabilization to restore a patient's chewing function. It is intended for single use only.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. The MS System (Denture) is intended for single use only.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. The MS System (Denture) is intended for single use only.	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. Ultra wide Fixture System is intended to be used in the molar region.
Structure	• Threaded Body Design • One Body Implant • 2/4mm gingival height neck • Ball-shaped head for O-Ring attachment.	• Threaded Body Design • One Body Implant • 2/4mm gingival height neck • Ball-shaped head for O-Ring attachment.	• Threaded Body Design • One Body Implant • 2/4mm gingival height neck • Ball-shaped head for O-Ring attachment.	• Internal Hex-connected • Submerged Fixture • Tapered body shape & Straight body shape
Thread Diameters	2.0, 2.5, 3.0	2.5, 3.0	2.0 ~ 3.0	3.5~6.8
Thread Lengths	8.5, 10.0, 11.5, 13.0, 15.0	10.0, 13.0, 15.0	8.5, 10.0, 13.0, 15.0	6.2~18.2
Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)

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Surface	SA (Sandblasted and Acid etched).	- SA(Sandblasted and Acid etched)	RBM (Resorbable Blast Media)	- SA(Sandblasted and Acid etched)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Packaging	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a tamper-evident outer package.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a outer box.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a outer box.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a tamper-evident outer package.
S.E.	The proposed device is substantially equivalent with respect to the intended use, structure, material, surface, sterilization and design with the legally marketed primary predicate device as well as the surface, sterilization and packaging of the legally marketed reference device. The slight difference in thread diameter and length is a simple size addition. The proposed device does not pose any new or increased risks as compared to the legally marketed primary predicate and reference devices.			

Device	**Proposed Device EM SA Implant System (Narrow Ridge)**	**Primary Predicate MS SA Implant System (Narrow Ridge)**	**Reference Device MS System**	**Reference Device HIOSSEN IMPLANT SYSTEM**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.	Osstem Co., Ltd.	Hiossen, Inc.
510(K) No.	New device	K122171	K083067	K140934
Design				
Intended use	The EM SA Implant System (NARROW RIDGE) is intended to be use in the treatment of missing mandibular central and lateral incisors to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. It is intended for delayed loading.	The MS SA Implant System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading.	The MS Implant System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS Implant (Narrow Ridge) is intended for single use only. 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. Ultra wide Fixture System is intended to be used

				in the molar region.
Structure	• Threaded Body Design • One Body Implant • 2.5/4mm gingival height neck • Integrated abutment head	• Threaded Body Design • One Body Implant • 2.5/4mm gingival height neck • Integrated abutment head	• Threaded Body Design • One Body Implant • 2/4mm gingival height neck • Integrated abutment head	• Internal Hex-connected • Submerged Fixture • Tapered body shape & Straight body shape
Thread Diameters	2.5, 3.0	2.5, 2.9	2.5, 3.0	3.5~6.8
Thread Lengths	8.5, 10.0, 11.5, 13.0, 15.0	8.5,10.0, 13.0, 15.0	8.5, 10.0, 13.0, 15.0	6.2~18.2
Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)
Surface	- SA(Sandblasted and Acid etched)	- SA(Sandblasted and Acid etched)	RBM (Resorbable Blast Media)	- SA(Sandblasted and Acid etched)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Packaging	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a tamper-evident outer package.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a outer box.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a outer box.	Secured in plastic ampule, housed in Tyvek-lidded blister tray, placed in a tamper-evident outer package.
S.E.	The proposed device is substantially equivalent with respect to the intended use, structure, material, surface, sterilization and design with the legally marketed primary predicate device as well as the surface, sterilization and packaging of the legally marketed reference device. The slight difference in thread diameter and length is a simple size addition. The proposed device does not pose any new or increased risks as compared to the legally marketed primary predicate and reference devices.			

Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include data from the following tests:

Biocompatibility Testing

The EM SA Implant System is manufactured using the same manufacturing process and same well known and well established material as the primary predicate device, the MS SA Implant System, K122171, therefore we reason it was not necessary to re-test biocompatibility in order to support the biological safety of the EM SA Implant System. Furthermore, as described in International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing when a new material is used that has not been identified in a primary predicate device. The proposed device is manufactured from standard raw material that is used in the primary predicate device and other currently marketed dental implant system. Therefore, no additional biocompatibility testing is required to establish substantial equivalence.

Sterilization Validation
The EM SA Implant System (manufactured using the same manufacturing process, material and utilizes the same sterilize barrier system) is gamma irradiated under the same conditions and process as the primary predicate device, the MS SA Implant System, K122171 and validated following ISO 11137 [2006] Sterilization of health care products – Requirements for Validation and Routine control – Radiation Sterilization guidelines, therefore we reason it was not necessary to re-test validation in order to support the sterilization validity of the EM SA Implant System.

Shelf Life
The EM SA shelf life is identical to the reference device HIOSSEN Implant System which has been validated for eight (8) years following ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems. The EM SA utilizes the exact same packaging materials & methods and is a medical grade titanium, nonmechanical, non-active device, therefore, degradation in performance characteristics is not likely over the established shelf life period. Therefore, no shelf-life validation or accelerated aging testing was performed.

Surface Treatment Characterization Testing
The EM SM Implant System is manufactured using the same manufacturing process, material and well known and well established surface treatment, SA (Sand blasted, Acid etched) as the predicate device, the MS SA Implant system, K122171, therefore no additional character testing was necessary to support the equivalency of the EM SA Implant System.

Fatigue Testing
The EM SA Implant System is manufactured using the same manufacturing process, material and very similar design, as the MS SA which was fatigue tested in accordance with ISO 14801:2003 Dentistry – Fatigue Test for Endosseous Dental Implants, we reason it was not necessary to re-test fatigue.

Clinical Performance Testing
No clinical performance report(s) is being submitted.

(7) Conclusion:
In accordance with the Federal Food Drug and Cosmetic Act, 21 CFR Part 807, and based on the data and information provided in this premarket notification, the proposed device, EM SA Implant System has established substantially equivalency to the primary predicate and reference device. An extensively comparison of the same design, intended use, structure, general shape and size, material and application method confirms the EM SA share many similarities with the primary predicate MS SA Implant System (K122171) and utilize the same sterilization method and packaging materials to the reference device Hiossen Implant System (K140934). The additional thread diameter and length is a simple size addition, a risk and mitigation measure for root-form endosseous dental implant in a FMEA risk analysis did not disclose any safety or health risk.