December 16, 2019

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

Re: K191751
Trade/Device Name: EM Provisional
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 16, 2019
Received: September 17, 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 Part 803) for devices or post marketing 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.
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*)

Device Name
EM Provisional

Indications for Use (*Describe*)

The EM Provisional is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of a permanent endosseous dental implant(s).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 6 510(k) Summary – 4 PAGES

(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 8, 2019

(2) Device Name:

- Proprietary Name: EM Provisional
- Classification Name: Implant, Endosseous, Root-form
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE

(3) Predicate Device:

Device	510(k)	Manufacturer
MS System (Provisional)	K072871	OSSTEM Co., Ltd.
Hiossen Implant System*	K140934	Hiossen, Inc.

*Reference device

(4) Description of Device:

The EM Provisional is a dental implant made of titanium alloy (Ti-6Al-4V) and is supplied sterile. The surface is machined finished and is intended to be surgically placed in the bone of the upper or lower jaw arches.

The EM Provisional 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 MS System (Provisional), OSSTEM Implant Co., Ltd, K072871

Device	Diameter(mm)	Thread Length(mm)
EM Provisional	∅1.8, ∅2.5	10.0, 13.0, 15.0

(5) Indication For Use:

The EM Provisional is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of a permanent endosseous dental implant(s).

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(6) Substantial Equivalence:

The information and date provided in this submission established the EM Provisional is substantially equivalent to the primary predicate device, OSSTEM MS System (Provisional) in (510(k) number K072871).

Device	Proposed Device EM Provisional	Predicate Device MS System (Provisional)	Reference Device HIOSSEN IMPLANT SYSTEM
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.	Hiossen, Inc.
510(K) No.	New device	K072871	K140934
Design			
Intended use	The EM Provisional is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implant(s).	The MS system (Provisional) is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.	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	• Screw form • One piece fixture and abutment	• Screw form • One-piece of Fixture and Abutment	• Internal Hex-connected • Submerged Fixture • Tapered body shape & Straight body shape
Diameters	1.8, 2.5	1.8, 2.5	3.5~6.8
Lengths	10.0, 13.0, 15.0	10.0, 13.0, 15.00	6.2~18.2
Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)
Surface	Machined finished	Machined finished	- SA(Sandblasted and Acid etched)
Sterilization	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 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 predicate device as well as the sterilization and packaging of the legally marketed reference device. The proposed device does not pose any new or increased risks as compared to the legally marketed predicate and reference devices.

Substantial Equivalence Conclusion

In accordance with the Federal Food Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, HIOSSEN, INC. concludes since the EM Provisional has the same design, intended use, structure, diameters, lengths, material, surface, sterilization as the predicate device, MS System (Provisional) (K072871) and same sterilization and packaging to the reference Hiossen Implant System (K140934) it is substantially equivalent. The propose device does not pose any new or increased risk as compared to both the legally marketed 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 Provisional is manufactured using the same manufacturing process and same well known and well established material as the predicate device, the MS System (Provisional), K072871, therefore we reason it was not necessary to re-test biocompatibility in order to support the biological safety of the EM Provisional.

Sterilization Validation

The EM Provisional (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 predicate device, the MS System (Provisional), K072871, therefore we reason it was not necessary to re-test validation in order to support the sterilization validity of the EM Provisional.

Surface Treatment Characterization Testing

The EM Provisional surface is manufactured using the same manufacturing process, material and is its surface is machined finished just as the predicate device, the MS System (Provisional), K072871, therefore no additional character testing was necessary to support the equivalency of the EM Provisional.

Fatigue Testing

The EM Provisional is manufactured using the same manufacturing process, material and same design, as the predicate MS System (Provisional), K072871. We reason based on the least burdensome principle that it was not necessary to re-test fatigue on the proposed device since both are the same device.

Compressive Strength Testing

The EM Provisional is manufactured using the same manufacturing process, material and same design, as the predicate MS System (Provisional), K072871. We reason based on the least burdensome principle that it was not necessary to re-test compressive strength on the proposed device since both are the same device.

Pull-out Testing

The EM Provisional is manufactured using the same manufacturing process, material and same design, as the predicate MS System (Provisional), K072871. We reason based on the least burdensome principle that it was not necessary to re-test pull-out on the proposed device since both are the same device.

Clinical Performance Testing

No clinical performance report(s) is being submitted.