May 21, 2019

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

Re: K183242
Trade/Device Name: ET IV SA Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 19, 2019
Received: April 22, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Malvina Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number (*if known*)
K183242

Device Name
ET IV SA Dental Implants

Indications for Use (*Describe*)

The ET IV SA Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide version is intended to be used in the molar region.

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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(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
Email: peter.l@hiossen.com

Date Prepared: May 21, 2019

(2) Device Name:

- Proprietary Name: ET IV SA Dental Implants
- Classification Name: Implant, Dental, Endosseous
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE

(3) Predicate Device(s):

	Device	510(k)	Manufacturer
Primary Predicate	HIOSSEN Implant System	K140934	HIOSSEN, INC.
Reference Device	Osstem Implant System	K161604	Osstem Implant Co., Ltd.

(4) Description of Device:

The ET IV SA Dental Implants are dental implants made from medical grade pure titanium metal (ASTM F67) and is supplied sterile. It is intended to be surgically placed in the bone of the upper or lower jaw arches.

The ET IV SA Dental Implant is available in various lengths from 7.0 to 15mm and diameters from 4.4 to 7.1mm, configurations are listed in the table below. The surface is SA: Sand blasted and Acid etched treated.

The ET IV SA Dental Implant is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

	Diameter (mm)	Length (mm)
ET IV SA	4.4	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
	4.8	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
	5.25	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
ET IV SA Ultra Wide	6.2	7.0, 8.5, 10.0, 11.5, 13.0
	7.1	7.0, 8.5, 10.0, 11.5, 13.0

(5) Indication For Use:

The ET IV SA Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide version is intended to be used in the molar region.

(6) Substantial Equivalence:
Hiossen, Inc. received premarket clearance for the primary predicate Hiossen implant System under premarket notification K140934. Hiossen, Inc modified the ETIII SA Fixture and ETIII SA Ultra-wide Fixture of the Hiossen Implant System. This modified ET III SA Fixture and ET III SA Ultra-wide Fixture is herewith submitted as a new 510(k) under the name ET IV SA Dental Implants.

The revision to the ET III SA Fixture and ET III SA Ultra-wide Fixture relates to the tapered body and thread. Table 1 shows the similarities and difference between the proposed device, ET IV SA Dental Implant and the primary predicate Hiossen Implant System – ET III SA Fixture and ET III SA Ultra-wide Fixture cleared under K140934 and reference device, Osstem Implant System – TSIV SA Fixture and TSIV Ultra-wide SA Fixture cleared under K161604.

The differences in the Indications for Use statements between the subject device and the primary predicate device and reference device such as the identification of the trade name of the device, removal of the word “retained” from the Indications for Use Statement does not alter the intended use of the subject device. Additionally, the Indications for Use Statement of the refence device provides instruction on the clinical use of the ø3.25mm and smaller sized device. The subject device does not contain a device in this size range and is not applicable.

Throughout this submission we show that the modifications does not affect or change affect the intended use of the device, indication for use, surgery type, structure, material, surface, sterilization method, shelf life and the fundamental scientific technology of the device when compared to the primary predicate device Hiossen Implant System (K140934) and reference device, Osstem Implant System, K161604. Therefore, the proposed device, ET IV SA Dental Implant is substantially equivalent to the primary predicate, Hiossen Implant System, K140934 and reference Osstem Implant System, K161604.

Table 1 Device Comparison

Device	Proposed Device ET IV SA Dental Implant	Primary Predicate Hiossen Implant System *ET III SA Fixture and ET III SA Ultra-wide Fixture (K140934)	Reference Device Osstem Implant System *TSIV SA Fixture & TSIV SA Ultra wide Fixture (K161604)
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Osstem Co., Ltd.
Indication for Use	The ET IV SA Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide version is intended to be used in the molar region.	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.	The Osstem 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. Products with diameter of less than 3.25mm should be used

			exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.
Surgery Type	One or two stage surgery	One or two stage surgery	One or two stage surgery
Structure	• Internal hex connection • Submerged fixture • Tapered body shape • 3 sided cutting edge with self-tapping • SA surface treatment	• Internal hex connection • Submerged fixture • Tapered body shape • 3 sided cutting edge with self-tapping • SA surface treatment	• Internal hex connection • Submerged fixture • Tapered body shape • 3 sided cutting edge with self-tapping • SA surface treatment
Body Diameter (D) (mm)	4.4, 4.8, 5.25 6.2* and 7.1*	3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.63, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6.0, 6.8	4.4, 4.8, 5.25, 6.2, 7.1
Length (mm)	7.0, 8.5, 10.0, 11.5, 13.0, 15.0 * the 6.2 and 7.1mm body diameter are not available in the 15mm length	6.2, 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	SA	SA
Sterilization Method	Radiation sterilization	Radiation sterilization	Radiation sterilization
Shelf life	8 years	8 years	8 years

Non-Clinical Performance Testing

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

Biocompatibility Testing

The ET IV Dental Implants is manufactured using the same manufacturing process and material as the predicate device, Hiossen Implant System, K140934, therefore it was deemed not necessary to re-test biocompatibility in order to support the biological safety of the ET IV Implants System as there is no new worst-case as compared to K140934.

Sterilization Validation

The ET IV Dental Implants (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, Hiossen Implant System, K140934, therefore was deemed not necessary to re-validate in order to support the sterilization validity of the ET IV Dental Implants System as there is no new worst-case as compared to K140934.

Fatigue Testing

The ET IV Dental Implants is manufactured using the same manufacturing process, material and structure, as the predicate device, Hiossen Implant System, K140934, we deemed it was not necessary to re-test fatigue testing. The fatigue test data of the ø 3.5 Hiossen Implant System, K140934 which was conducted per ISO 14801:2007 Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants, is applicable to the ET IV Dental Implants as there is no new worst-case as compared to K140934.

Conclusion

The ET IV SA Dental Implants are modified Hiossen Implant System – ET III SA Fixture and ET III SA Ultra-wide Fixture (K140934) where the modification does not affect or change the intended use of the device or the fundamental scientific technology of the device. It has the same indication for use, surgery type, structure, material, surface, sterilization method, and shelf life with the primary predicate device Hiossen Implant System (K140934). Based on the testing provided, biocompatibility, sterilization and fatigue, support that the ET IV SA Dental Implants is substantial equivalent to the predict device, Hiossen Implant System, K140934 and reference device, Osstem Implant System, K161604. Any differences in characteristics between the proposed device and the primary predicate and reference does not raise different or additional questions of substantial equivalence.