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 27, 2016

HiOSSEN Inc.
David Kim
Manager
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K153332
Trade/Device Name: ETIII SA Fixture System (Ø 3.2mm)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 27, 2016
Received: September 28, 2016

Dear David Kim:

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

Hiossen Inc.
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www.hiossen.com

Indications for Use Statement

510(k) Number K _____

Device Name : The ETIII Fixture System (Ø3.2mm)

Indication for use :
The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and central incisor, 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.

Prescription Use___X____ (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (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)

Section 008

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510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : Sept. 27, 2016

1. Company and Correspondent making the submission:

- Submitter's Name :	HiOSSEN Inc.
- Address :	85 Ben Fairless Dr. Fairless Hills PA 19030
- Telephone No.	888 678 0001
- Contact :	Mr. David Kim

2. Device :

Trade or (Proprietary) Name :	ETIII SA Fixture System (Ø3.2)
Common or usual name :	Endosseous Dental Implant
Regulation Number:	21 CFR 872.3640
Regulation Name:	Endosseous Dental Implant
Regulatory Class:	Class II
Product Code:	DZE, NHA

3. Predicate Device:
Primary Predicate: HIOSSEN IMPLANT SYSTEM (HIOSSEN Inc., K140934)
Referenced Predicate #1: MS SA IMPLANT SYSTEM (HIOSSEN Inc., K122171)
Referenced Predicate #2: NobelActive 3.0 (NobelBiocare, K102436)

4. Description :

1) The ETIII SA Fixture System (Ø3.2) is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

2) The ETIII SA Fixture System (Ø3.2mm) is made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and central incisor, 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.

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3) Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile.		
Material	Alloyed Titanium (ASTM F136)		
Surface	SA surface treatment (Sand blasted and Acid etched)		
	Diameter (mm)	Length (mm)	Connection
Dimension	3.2	8.7, 10.2, 11.7, 13.2, 15.2	Mini

4) Component

Mount Set	
Description	To be used for easy implanting of the Fixture
Material	Alloyed Titanium (ASTM F136)
Diameter (mm)	4.8
Length (mm)	16
Connection	Mini
Cover Screw	
Description	To be used to protect the exposed platform of the implant during healing period.
Material	Pure Titanium (ASTM F 67)
Diameter (mm)	3.1
Length (mm)	4.75
Connection	Mini

Substantial Equivalence

	Proposed device	**Primary predicate device**	**Reference predicate device**	**Reference predicate device**
	ETIII SA Fixture System (Ø3.2mm)	**Hiossen Implant System**	**MS SA Implant System**	**NobelActive 3.0**
Design				
510(K) No.	N/A	K140934	K122171	K102436

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Indication for use	The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and central incisor, 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.	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 MS SA Implant (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 NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth,in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.
Surgery type	One or two stage Surgery	One and two stage Surgery	One stage Surgery	One and two stage Surgery
Structure	- Internal Hex - Bone Level Implant - Straight body shape - 3 sided cutting edge with self-tapping	- Internal Hex - Bone Level Implant - Tapered body shape - 3 sided cutting edge with self-tapping	- One Body Implant - Straight body shape - Threaded body design - 2 sided cutting edge	-Internal Hex - Bone Level Implant
Body Diameter	3.2 mm	3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.63, 4.65, 4.9, 5.0, 5.1, 5.05, 5.08, 5.92, 5.95, 6.8 mm	2.5, 2.9 mm	3.0 mm
Length	8.7, 10.2, 11.7, 13.2, 15.2 mm	6.2, 7.2, 8.2, 8.7, 9.7, 10.2, 11.2, 11.7, 12.7, 13.2, 15.2, 18.2 mm	8.5, 10, 11.5, 13 mm	10, 11.5, 13, 15 mm
Material of Fixture	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Grade 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA(Sandblasting & Acid etching)	SA(Sandblasting & Acid etching)	SA(Sandblasting & Acid etching)	TiUnite
Steriliza-tion	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	8years	8years	8 years	n/a

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Differences	The indications for use: The indication for use statement for the proposed device is not identical to the predicate device(K140934); however, the difference does not alter the general intended use of dental implant. Both the subject and predicate devices have the same intended use for the replacement of missing teeth. And the indication for use of proposed device is very similar with predicate device, K102436. Material: The proposed device is made with alloyed titanium (Ti-6Al 4V) and the predicate device, K140934 is made with pure titanium (Ti CP4). The difference in material is insignificant chemical composition. And another predicate device, K122171 is made with alloyed titanium(Ti-6Al-4V)
Similarities And S.E	Proposed device, ETIII SA Fixture System (Ø3.2mm) is same with predicate devices in intended use (K140934 / K102436), material (K122171), and surface treatment (K140934).

5. Indication for use :
The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and central incisor, 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.

6. Summary of nonclinical testing
Hiossen predicate K140934 was relied upon for sterility, shelf-life and biocompatibility. Additionally LAL testing per USP <85> was conducted for the subject device.

Non-clinical testing data submitted to demonstrate substantial equivalence includes adaptation accuracy for rotation angle and gap, static and dynamic fatigue test according to “Guidance for industry and FDA staff Class Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” All tests were conducted in accordance with relative standards without any discrepancies.

Test Items	Standard
Subchronic Toxicity test (ISO 90 Days, Bone)	ISO 10993-11 , ISO 10993-6
Bacterial reverse mutation test (Genotoxicity test)	ISO 10993-3, ISO 10993-12
Chromosome aberration test (Genotoxicity test)	ISO 10993-3, ISO 10993-12
Cytotoxicity test	ISO 10993-5, ISO 10993-12
Sterility test	USP 36 <71>
Skin sensitization test (GPMT)	ISO 10993-10

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Oral Mucosa Irritation test	ISO 10993-10
Acute Systemic Toxicity test	ISO 10993-11
Pyrogen test	ISO 10993-11, USP 36 <151>

7. Summary of clinical testing
No clinical studies are submitted.

8. Conclusions
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 that the The ETIII SA Fixture System (Ø3.2) is substantially equivalent to the predicate devices as described herein.