DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 21, 2016

Hiossen Inc.
Mr. David Kim
RA/QA Manager
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K151626
Trade/Device Name: ETIII Bio-SA Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 20, 2016
Received: June 20, 2016

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of July 21, 2016. 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" (21CFR 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 007

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

Indications for Use Statement

510(k) Number K 151626

Device Name : ETⅢ Bio-SA Fixture System

Indication for use : ETIII Bio-SA Fixture 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 terminal or intermediate abutment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical procedures. 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)

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

510(k) Summary

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

Date : July 20, 2016

1. Company and Correspondent making the submission:

1) Submitter's Name :	HIOSSEN Inc.
2) Address :	85 Ben Fairless Dr. Fairless Hills PA 19030
3) Telephone No.	888 678 0001
4) Contact :	Mr. David Kim

2. Device :

Trade or (Proprietary) Name :	ETIII Bio-SA Fixture System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
   1)Primary Predicate : ETIII Bio-SA Fixture System / HIOSSEN INC. / K112532
   2)Reference Predicate : HIOSSEN Implant System / HIOSSEN INC. / K140934
   3)Reference Predicate : SLActive / Straumann USA / K053088

4. Description :

   1) Indication for use → same as the primary predicate device, K112532
   ETIII Bio-SA Fixture 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 terminal or intermediate abutment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical procedures. It is intended for delayed loading.

2) Technology

(1) Design Features

ETIII Bio-SA Fixture has features of single threads, internal hex connection, taper body, and Bio-SA surface treatment.

(2) Raw material used

ETIII Bio-SA Fixture System is permanent dental implant made with Pure titanium Grade 4 (ASTMF67-06)

(3) Surface treatment

The proposed device is sandblasted, acid etched, coated with calcium phosphate by immersing and then finally coated with hydrophilic materials (glucose and NaCl with saline concentrations). Coating with hydrophilic material is added to the predicate device(ETIII Bio-SA Fixture, K112532) to improve a cosmetic characteristic(darker than predicate device, K112532).

5. Device comparison table

The proposed device, ETIII Bio-SA Fixture System is similar to other commercially and legally available medical devices (ETIII Bio-SA Fixture System, K112532 and HIOSSEN IMPLANT SYSTEM, K140934, Straumann SLActive Implants, k053088) based on the intended use, the technology used, the claims, the material used and performance characteristics.

- Substantial Equivalence Matrix

	Proposed device	**Primary Predicate devices**	**Reference(1) Predicate devices**	**Reference(1) Predicate devices**
	ETIII Bio-SA Fixture	**ETIII Bio-SA Fixture (K112532)**	**HIOSSEN IMPLANT SYSTEM (K140934)**	**SLActive Implants (K053088)**
Manufac-turer	HIOSSEN INC.	HIOSSEN INC.	HIOSSEN INC.	Straumann USA,LLC
Design				

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

Intended Use	The ETIII Bio-SA Fixture 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 over-denture restorations, and terminal or intermediate abut-ment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical pro-cedures. It is not for immediate load.	The ETIII Bio-SA Fixture 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 over-denture restorations, and terminal or intermediate abut-ment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical pro-cedures. It is not for immediate load.	The ETIII SA Fix-ture System is indi-cated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including ;cemented retained, screw retained, or over-denture restorations, and terminal or intermediate abut-ment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical pro-cedures. It is not for immediate load.	SLActive implants are for single-stage or two-stage surgical procedures. SLActive implants are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately loaded cases.
Structure	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-BONE CONTROL DESIGN™ -Apically Tapered
Connection Type	Internal hex connection	Internal hex connection	Internal hex connection	CROSSFIT® CONNECTION
Diameter (D)	3.77, 3.75, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.10	3.77, 3.75, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.10	3.5~5.0	Ø 3.3, Ø 4.1 and Ø 4.8 mm
Length (mm)	7.2 , 8.7 , 10.2 , 11.7 , 13.2 15.2	7.2 , 8.7 , 10.2 , 11.7 , 13.2 15.2	6.0~18	8, 10, 12, 14 and 16 mm
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)
Surface	Bio-SA (SA + D-glucose +Nacl)	Bio-SA (SA + coating with calcium hosphate)	SA (Acid etched)	SLActive

Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Difference	There are no differences in intended use, materials, fundamental scientific technology, etc. between proposed device and primary predicate device, ETIII BA Fixture, K112532. Only difference between them is additional hydrophilic materials applied on the surface is intended to aid in the wettability.			
S.E.	The intended use, material used, design, and fundamental scientific technology, etc. of the propose device and the predicate device are similar. The proposed device is substantially equivalent to the predicate devices.			

7. Summary of tests

Wettability and blood affinity of Bio-SA surface with hydrophilic material compared to existing BA surface, the primary predicate device (K112532) and the reference predicate device(K123784) has been observed. The materials(Glucose and NaCl) of the primary predicate device(K112532) and the material(NaCl) of the reference predicate device(K123784) used for wetting ability that simulate the implantation of product.

Surface analysis and characteristic testing of the hydrophilic material was conducted by EDS, FE-SEM and ICP-AES was conducted,

The biocompatibility tests have been conducted in accordance with ISO 10993-1 and FDA G95-1 Guidelines. The subject device is classified Implant Devices and Tissue/Bone (Contact Duration: c - Permanent [>30 days].

Test Items	Standard
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Irritation	ISO 10993-10
Systemic Toxicity (Acute)	ISO 10993-11
Sub-acute(sub-chronic Toxicity)	ISO 10993-6/11
Chromosome aberration	ISO 10993-3 /12
Implantation	ISO 10993-6
Pyrogen	ISO 10993-11

All biocompatibility tests have also been conducted according to the related standards and no discrepancies have been observed.

8.Animal test

a. Information on test animals

i. Species (strain) /gender: Beagle from Korea, male

ii. Weight : 10kg
iii. Source: ORIENTBIO Inc. in Korea
iv. Number of test animals : 12
v. Acclimation and quarantine
-. Acclimation for 2weeks
-. Quarantine ; Animal Research Institute, School of Dentistry, Seoul National University, Seoul, Korea (anti body test, heartworm test, ant helminth administration, DHPPL inject, Rabies inject, Ivermectin inject, etc.)

b. Results: Comparative testing of the BA and SA Implant bodies was conducted for"
i. Removal torque after two weeks and eight weeks were measured.
ii. Length of bone loss from marginal bone level was measured by optical images at 2,4, and 8 weeks
iii. Bone-to-implant contact was measured at 2,4, and 8 weeks

9.Shelf-life validation (ASTM F1980) and sterilization validation conducted to ISO 11137-2

10. Summary of clinical testing

Investigated patient ages, genders, insertion areas, specific treatment (indications), bone distributions, diameter and length of fixtures used, treatment (bone level or non-bone level procedures), initial fixation of implant during insertion, final prosthesis date, failure and complications.

Clinical data was provided for 45 subjects ages 18 or older with a total of 66 implants placed. The study evaluated primary stability, sensory abnormality, bone resorption, peri-implantitis, complications, delayed treatment, fracture, and implant body failure. The final follow-up was 13.7 to 18.2 months with an average of 16.3 months revealed 100% success rate for survival and no adverse events after the 1 year follow-up.

11. Conclusion:

Based on the information provided in this premarket notification HIOSSEN concludes that the ETIII BA Fixture System is substantially equivalent to the predicate devices as described herein.