K103537

HIOSSEN
Hiossen Inc.
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www.hiossen.com

MAR 10 2011

510(k) Summary

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

Date : Nov 11th, 2010

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. Patrick Lim

2. Device :

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

3. Predicate Device :
The HGIII Ultra wide Fixture System, Hiossen Inc, K093889
The ETIII SA Fixture System, Hiossen Inc, K101096
The HU/HS/HG Prosthetic System, Osstem Implant Co., Ltd, K081575

4. Description :
1) The ETIII SA Ultra wide Fixture is dental implant made of titanium metal intended to be used in the molar region and surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The ETIII SA Ultra wide Fixture is composed of single threads with internal hex connection taper body of bone level. The surface is SA, Sandblasting and Acid etching, treated.

2) The ET Healing Abutment is used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.

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Class Ⅱ Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the GSⅢ Fixture(or HGⅢ Fixture) and an angled abutment in support of the ETⅢ SA Ultra Wide Fixture.
Therefore, the fatigue test result of GSⅢ Fixture System (or HGⅢ Fixture System) can be used as a proof of ETⅢ SA Ultra Wide Fixture since ETⅢ SA Ultra Wide Fixture has large diameter.

8. Conclusion :
Based on the information provided in this premarket notification HiOSSEN concludes that the ETⅢ SA Ultra wide System is substantially equivalent to the predicate device as described herein.

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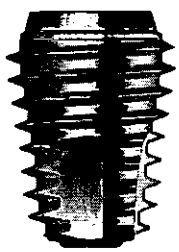
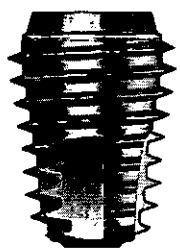
3) The ETⅢ SA Ultra wide System is same to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

4) The ETⅢ SA Ultra wide System is substantially equivalent in design, function and intended use to HGⅢ Ultra wide Fixture System (K093889), ETⅢ SA Fixture System (K101096) of Hiossen Inc. and Healing Abutment of HU/HS/HG Prosthetic System (K081575) of Osstem Implant Co., Ltd.

- Substantial Equivalence Matrix

	ETⅢ SA Ultra wide Fixture	Predicate devices	
		HGⅢ Ultra wide Fixture	ETⅢ SA Fixture
Manufacturer	Hiossen Inc	Hiossen Inc	Hiossen Inc
510(k) Number	New	K093889	K101096
Design			
Indication for use & Procedural Precautions	The ETⅢ SA Ultra wide 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 Ultra wide System is for single and two stage surgical procedures. It is not for immediate load. The HGⅢ Ultra wide System is intended to be used in the molar region.	The HGⅢ Ultra wide 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 HGⅢ Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The HGⅢ Ultra wide Fixture System is intended to be used in the molar region.	The ETⅢ 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 SA Fixture System is for single and two stage surgical procedures. It is not for immediate load.

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Diameter (D) *Length (mm)	Refer to the Table 1		
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)
Surface Treatment	SA (Sandblasting and Acid etching)	RBM (Resorbable Blast Media)	SA (Sandblasting and Acid etching)
Packaging	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	5 years	5 years	5 years

ETⅢ SA Ultra wide Fixture		Predicate devices			
		HGⅢ Ultra wide Fixture		ETⅢ SA Fixture	
(Ø)	(mm)	(Ø)	(mm)	(Ø)	(mm)
-	-	-	-	3.75	8.7, 10.2, 11.7, 13.2, 15.2
-	-	-	-	4.25	7.2, 8.7, 10.2, 11.7, 13.2, 15.2
-	-	-	-	4.6, 4.65	7.2, 8.7, 10.2, 11.7, 13.2, 15.2
-	-	-	-	5.05, 5.08, 5.1	7.2, 8.7, 10.2, 11.7, 13.2, 15.2
5.9, 5.92, 6.0	7.2, 8.2, 9.7, 11.2, 12.7	5.9, 5.92, 6.0	7.2, 8.2, 9.7, 11.2, 12.7	-	-
6.8, 6.82	7.2, 8.2, 9.7, 11.2, 12.7	6.8, 6.82	7.2, 8.2, 9.7, 11.2, 12.7	-	-

Table 1. Diameter and length (ETⅢ SA Ultra wide Fixture and Predicate devices)

5. Indication for use :

The ETⅢ SA Ultra wide 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 SA Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The ETⅢ SA Ultra wide Fixture System is intended to be used in the molar region.

6. Review :

The ETⅢ SA Ultra wide System has same material, indication for use and technological characteristics as the predicate device.

The ETⅢ SA Ultra wide System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing

Fatigue testing was conducted according to the "Guidance for industry and FDA staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Patrick Lim
Regulatory Affairs
HiOSSEN Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

MAR 10 2011

Re: K103537
Trade/Device Name: ETIII SA Ultra wide System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 7, 2011
Received: February 8, 2011

Dear Mr. Lim:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 103537

Device Name : ETIII SA Ultra wide System

Indication for use : The ETIII SA Ultra wide 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 SA Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The ETIII SA Ultra wide Fixture System is intended to be used in the molar region.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103537