K101096

HIOSSEN

Hiossen Inc.
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Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

OCT 8 2010

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 : April 6th, 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 :	HTIII SA Fixture System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
The HGIII Fixture System, HiOSSEN Inc, K093352
The Straumann Standard Implant, Institut Straumann Ag, K061176

4. Description :
1) The HTIII SA Fixture System is dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.

2) HTIII SA Fixture is composed of single threads with internal hex connection taper body of bone level for two stage surgery. It has SA surface.

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

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4) The HTIII SA Fixture System is substantially equivalent in design, function and intended use to the HGIII Fixture System (K093352) of HiOSSEN Inc. and Straumann Standard Implant (K061176) of Institut Straumann Ag.

- Substantial Equivalence Matrix

	HTIII SA Fixture	Predicate devices	
		HGIII Fixture (K093352)	Straumann Standard Implant (K061176)
Manufacturer	HiOSSEN Inc.	HiOSSEN Inc.	Institut Straumann Ag
Intended Use	The HTIII 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 HTIII SA Fixture System is for single and two stage surgical procedures. It is not for immediate load.	The HGIII 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 Fixture System is for single and two stage surgical procedures. It is not for immediate load. The Ultra wide Fixture System is intended to be used in the molar region.	Straumann Regular Neck and Narrow Neck implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used. The Straumann Regular Neck Implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients for single-stage or two-stage surgery. The Straumann Narrow Neck implants are intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the Narrow Neck implant is indicated for replacement of single lateral incisors in the maxilla and lateral and central incisors in the

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			mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibule-oral bone is restricted (minimum 5 mm). The Narrow Neck implant can also be used as a support for a full arch implant-born restoration, but only in conjunction with a standard Straumann 4.1 mm dental implant.
Structure	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Straight body Type -Non-submerged fixture
Connection Type	Internal hex connection	Internal hex connection	Internal connection
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	SA	RBM	SLA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	5 years	5 years	5 years
S & E	The HTⅢ SA Fixture System has same material, indication for use and design as the HGⅢ Fixture System. But they have different surface treatment. The HTⅢ SA Fixture System has similar surface treatment as the Straumann Standard Implant.		

5. Indication for use :
The HT III 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 HT III SA Fixture System is for single and two stage surgical procedures. It is not for immediate load.

6. Review :
The HTⅢ SA Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

The HTⅢ SA Fixture 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.

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7. Summary of nonclinical testing

The biocompatibility test was conducted according to ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO 10993-11. The surface treatment test was conducted. The biocompatibility and surface treatment test results were similar to previously cleared predicate device.

8. Conclusion :

Based on the information provided in this premarket notification HiOSSEN concludes that the HTIII SA Fixture System is substantially equivalent to the predicate device as described herein.

HTIII SA Fixture		Predicate devices			
		HGIII Fixture (K093352)		Straumann Standard Implant (K061176)	
(Ø)	(mm)	(Ø)	(mm)	(Ø)	(mm)
3.75	8.7, 10.2, 11.7, 13.2, 15.2	3.75	8.7, 10.2, 11.7, 13.2, 15.2	3.3	8.0, 10.0, 12.0, 14.0, 16.0
4.25	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	4.25	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	4.1	6.0, 8.0, 10.0, 12.0, 14.0, 16.0
4.6, 4.63, 4.65	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	4.6, 4.63, 4.65	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	4.8	6.0, 8.0, 10.0, 12.0, 14.0
5.05, 5.08, 5.1	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	4.8	6.0, 8.0, 10.0, 12.0

Table 1. Diameter and length (HT3 SA Fixture and Predicate devices)

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
Manager
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

OCT 8 2010

Re: K101096
Trade/Device Name: HTIII SA Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 29, 2010
Received: September 29, 2010

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

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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Device Name : HTIII SA Fixture System

Indication for use : The HT III 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 HT III SA Fixture System is for single and two stage surgical procedures. It is not for immediate load.

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

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