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

January 30, 2017

HIOSSEN Inc.
Mr. David Kim
RA Manager
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K162390
Trade/Device Name: ET Hybrid Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 30, 2016
Received: December 30, 2016

Dear Mr. 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,

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

SECTION 006

Indications for Use Statement

510(k) Number K 162390

Device Name : ET Hybrid Abutment

Indication for use : ET Hybrid Abutment is a customized abutment intended for use with HIOSSEN ET dental implant in the edentulous or partially edentulous maxilla or mandible to provide support for prosthetic restorations such as crowns and bridges. All digitally designed copings for use with the ET Hybrid Abutment for CAD/CAM are intended to be sent to a HIOSSEN Inc. manufacturing facility for manufacture.

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)

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SECTION 007

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: Jan. 26, 2017

1. **Company and Correspondent making the submission:**

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

2. **Device:**

Trade or (proprietary) Name:	ET Hybrid Abutment
Common or usual Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	Class II
Product Code:	NHA

3. **Predicate Device:**

Primary : K132219 / Straumann Variobase Abutments / Institut Straumann AG

Reference : K100245 / HS/HG Prosthetic System / Osstem Implant Co., Ltd.

Reference : K123627 / ET Smartfit Abutment / HIOSSEN INC.

4. **Description:**

ET Hybrid Abutment is intended to be placed onto Hiossen dental implants to provide support for customized prosthetic restorations such as crowns and bridges. The proposed devices are composed of ET Link Abutment and Coping. The ET Link Abutment is pre-manufactured abutment by Hiossen Inc. only and the coping would be manufactured by Hiossen only with design input using CAD/CAM software from both by dental laboratories and by Hiossen Inc. The final device of ET Hybrid Abutment is under controlled by Hiossen's Quality System and provided to the customer. ET Hybrid Abutment is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. Titanium alloy is the raw material for the Link Abutment and Zirconia material is for the Coping. The ET Hybrid Abutment gives the flexibility to design customized prosthetics. The coping is straight only and the ET Link abutment is not intended to provide an angle and/or divergence correction.

The design limitation for coping is defined as below.

Code	ETCMAMNZS / ETCMAMHZS	ETCMARNZS, ETCMARHZS
Diameter (D)	4.2~15 (mm)	4.7~15 (mm)
Wall Thick.	0.35~0.55(mm)	0.40~0.65 (mm)
Post Height(H)	4~16 (mm)	4~16 (mm)
Post Wall Thick.(t)	0.7~2.7 (mm)	1.2~4.2 (mm)
Post Diameter (d)	2.5~6.5 (mm)	3.0~9.0 (mm)
Gingival Margin Height (G/H)	3.5~8.5 (mm)	3.5~8.5 (mm)

The coping is straight only and the ET Link abutment is not intended to provide an angle and/or divergence correction.

The proposed devices are compatible with the implant systems below.

No.	**510(K)**	**Proprietary name**	**Manufacture**
1	K101096	ET III SA Fixture System	HIOSSEN. Inc
2	K103537	ETIII SA Ultra Wide System	HIOSSEN. Inc
3	K112532	ET III Bio-SA Fixture System	HIOSSEN. Inc
4	K123471	ETII SA FIXTURE SYSTEM	HIOSSEN. Inc
5	K140934	HIOSSEN IMPLANT SYSTEM	HIOSSEN. Inc
6	K151626	ET III NH System	HIOSSEN. Inc

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- Substantial Equivalence Matrix

Part Name	Proposed devices	Primary predicate devices	Reference predicate devices	
	ET Hybrid Abutment	**Straumann Variobase Abutments**	**The HS/HG Prosthetic System**	**ET Smartfit Abutment**
510K	Proposed	K132219	K100245	K123627
Material	Titanium Alloy Ti-6AL 4V	Titanium Alloy Ti-6AL 4V	Titanium Alloy (most abutments in the submission) Zirconia (Ziocera angled abutment)	Titanium Alloy Ti-6AL 4V
Manufacturer	HIOSSEN INC.	Institute Straumann AG	Osstem Implant Co., Ltd	HIOSSEN INC
Description	ET Hybrid Abutment is intended to be placed onto Hiossen dental implants to provide support for customized prosthetic restorations such as crowns and bridges. The proposed devices are composed of ET Link Abutment and Coping. The ET Link Abutment is pre-manufactured abutment by Hiossen Inc. only and the coping would be manufactured by Hiossen only with design input using CAD/CAM software from both by dental laboratories and by Hiossen Inc. The final device of ET Hybrid Abutment is under controlled by Hiossen's Quality System and provided to the customer. ET Hybrid Abutment is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. Titanium alloy is the raw material for the Link Abutment and Zirconia material is for the Coping. The ET Hybrid Abutment gives the flexibility to design customized prosthetics. The coping is straight only and the ET Link abutment is not intended to provide an angle and/or divergence correction.	The Straumann Variobase Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann Variobase Abutments are available to fit Straumann dental implant platforms NNC (Narrow Neck CrossFit), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), and RC (Regular CrossFit). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the dental laboratory using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via validated Straumann milling.	The HS/HG Prosthetic System is device made of titanium, titanium alloy, POM and PC and Zirconia intended for use as an aid in prosthetic restoration. It consists of Abutment, Protect Cap and/or Abutment Screw. Their surfaces are partially Tin coated and uncoated. The HS/HG Prosthetic 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. **Use the ZioCera Abutment for implant restoration of single tooth or multiple teeth and for aesthetic restoration or when existing metal abutment cannot be used.**	The ET SMARTFit Abutment is device made of titanium alloy intended for use as an aid in prosthetic restoration. That is customized abutment considering shape of the finial prosthesis based on the patient's mouth model using CAD/CAM system during the manufacturing . The ET SMARTFit Abutment is used for cement-retained crowns and bridges using customized abutment considering based on the patient's mouth using CAD/CAM system. Use only the basal screws provide for the Custom Abutment. The surgical procedure for custom abutment is the same as the surgical procedure for the cement-retained abutments.

Indication for use	ET Hybrid Abutment is a customized abutment intended for use with HIOSSEN ET dental implant in the edentulous or partially edentulous maxilla or mandible to provide support for prosthetic restorations such as crowns and bridges. All digitally designed copings for use with the ET Hybrid Abutment for CAD/CAM are intended to be sent to a HIOSSEN Inc. manufacturing facility for manufacture.	The Straumann Variobase' Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	HS/HG Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	ET SmartFit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design	 Two-piece Type	 Two-piece Type	 One-piece Type	 One-piece Type
Diameter (mm)	Ti- Base: 4.0/4.5 Two-piece : 4.2~15	Ti- Base : 2.8~3.3 Two-piece : N/A	5.5/6.5	4~15
Height (mm)	Ti- Base : 3.2 Two-piece : 4~16	Ti-Base : 3.5 Two-piece : N/A	3.0, 4.0 (G/H)	3~18

S E	ET Hybrid Abutment has the similar intended use for, technological characteristics as predicate devices, K132219 Straumann Variobase Abutments (K132219) of Institut Straumann AG. Both devices are customized abutments. Especially Variosbase abutment and the subject devices are similar manufacturing processes. The Ti-base part is pre-milled and made of titanium material and coping is designed by the dental laboratory and manufacturer using the CAD software and milled by manufacturer only. The only differences are connection structure and insignificant shapes. The connection and shape are only for the manufacturer's design and compatible to their own dental implant design. The ET Smart Fit abutment as the referenced predicate has the same manufacturing process and facility, similar dimensions but only difference is a material on the top (Zirconia vs Titanium). The zirconia material is widely used in the Dental industry and the materials similarity is applicable to the Zirconia abutment (HS/HG Prosthetic System by Osstem, K100245). This subject device is manufactured using identical materials and manufacturing processes to a previously cleared predicate.

5. Indication for Use :

ET Hybrid Abutment is a customized abutment intended for use with HIOSSEN ET dental implant in the edentulous or partially edentulous maxilla or mandible to provide support for prosthetic restorations such as crowns and bridges. All digitally designed copings for use with the ET Hybrid Abutment for CAD/CAM are intended to be sent to a HIOSSEN Inc. manufacturing facility for manufacture.

6. Technological Characteristics

The proposed device has same technological characteristics as the predicate device of K132219 Straumann Variobase Abutments (K132219) of Institut Straumann AG. ET Hybrid Abutment and predicate device are composed of ET Link Abutment and Coping. ET Link Abutment is pre-manufactured abutment made with Titanium alloy and Coping is customized with Zirconia. The only differences are connection structure and insignificant shapes.

7. Summary of nonclinical testing

Hiossen, Inc. predicate K123627 and K100245 was relied upon for biocompatibility. The subject device is manufactured using identical materials and manufacturing processes to a previously cleared predicates below. No additional biocompatibility testing was necessary for this device. The chemical composition, body contact and sterilization method are the same as the predicate devices. (Category: Implant Device, Contact: BONE / TISSUE, Contact Duration: C-Permanent More than 30 days) Additional non-clinical testing data submitted to demonstrate substantial equivalence includes steam sterilization validation according to ISO 17665-1, ISO/TS 17665-2 for gravity displacement on unwarp condition. All tests were conducted in accordance with relative standards without any discrepancies.

TEST ITEM	STANDARD
Steam sterilization Validation	ISO 17665-1, ISO/TS 17665-2

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

9. Conclusions
   The documentation submitted in this premarket notification demonstrates that the ET Hybrid Abutment is substantially equivalent to the predicate devices.