January 11, 2018

HIOSSEN Inc.
David Kim
Regulatory Affair Manager
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K170421
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 12, 2017
Received: December 12, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -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

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SECTION 006

Indications for Use Statement

510(k) Number K170421

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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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. 11, 2018

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:

1) Primary : ET Hybrid Abutment K162390 / Hiossen, Inc.

2) Reference: Straumann Variobase Abutments (K132219, Institut Straumann AG)

3) Reference: ET SmartFit Abutment (K123627, Hiossen Inc.)

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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 and bonded into the ET Link Abutment by Hiossen only with design input using CAD 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 design limitation for coping is defined as below.

Code	ETCMAMNZS	ETCMAMHZS	ETCMARNZS	ETCMARHZS
(A) Angulation	0 ~ 30 (°)		0 ~ 30 (°)	
(B) Gingival Diameter	4.2~15 (mm)		4.7~15 (mm)	
(C)Total Height	4.5~16 (mm)		4.5~16 (mm)	
(D)Contact Diameter	Ø4.2		Ø4.7	
(E)Wall Thickness	Minimum 0.35 (mm)		Minimum 0.44 (mm)	
(F)Gingival Height	0.5 ~ 8.0 (mm)		0.5 ~ 8.0 (mm)	
(G)Post Diameter	2.0~6.5 (mm)		3.0~9.0 (mm)	
(H)Post Height	4~16 (mm)		4~16 (mm)	

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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 BA 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 Predicates	
	ET Hybrid Abutment	**ET Hybrid Abutment**	**Straumann Variobase Abutments**	**ET Smartfit Abutment**
510K	Proposed	K162390	K132219	K123627
Material	Titanium Alloy Ti-6AL 4V Zirconia Oxide	Titanium Alloy Ti-6AL 4V Zirconia Oxide	Titanium Alloy Ti-6AL 4V Zirconia Oxide	Titanium Alloy Ti-6AL 4V
Manufacturer	HIOSSEN INC.	HIOSSEN INC.	Institut Straumann AG	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 and bonded into the ET Link Abutment by Hiossen only with design input using CAD 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 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.	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	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.

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Description (Continue)	ET Hybrid Abutment is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The ET Hybrid Abutment gives the flexibility to design customized prosthetics.	ET Hybrid Abutment is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. 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.	using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via validated.	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 are intended to be sent to a HIOSSEN Inc. manufacturing facility for manufacture.	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 are intended to be sent to a HIOSSEN Inc. manufacturing facility for manufacture.	The Straumanho Variobase' Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straiuman Variobase Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	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 [Abutment + Screw]	 Two-piece Type [Abutment + Screw]	 Two-piece Type [Abutment + Screw]	 Two-piece Type [Abutment + Screw]
Diameter (mm)	Ti- Base: 4.0/4.5 Two-piece : 4.2~15	Ti- Base: 4.0/4.5 Two-piece : 4.2~15	Ti- Base : 2.8~3.3 Two piece : N/A	4~15
Height (mm)	Ti- Base : 3.2 Two-piece : 4.5~16	Ti- Base : 3.2 Two-piece : 4.5~16	Ti-Base : 3.5 Two piece : N/A	3~18
Angle (º)	0 ~ 30	0	0 ~ 30	0 ~ 30

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S.E	The propose device has the similar intended use for, technological characteristics as predicate devices, ET Hybrid Abutment(K162390) and ET SmartFit Abutment(K123627) by Hiossen,Inc. , Straumann Variobase Abutment(K132219) of Institut Straumann AG. Those devices are the customized abutment devices. Especially, the ET Hybrid Abutment system(K162390, Primary predicate) and Variobase Abutment system(K132219, Reference predicate) are similar process. The Ti-base(or link) part is pre-milled and made of titanium material and coping part is designed by the dental laboratory and manufacturer using the CAD software and milled and bonded into ET Link Abutment by manufacture only. The only differences with the reference predicate (Variobase Abutment,K132219) are connection structure and insignificant shapes. The shape are only for the manufacturer's properties such as design and compatible to their own dental implant design. The primary predicate (ET Hybrid Abutment,K162390) is almost same structure and dimension but it's straight only which is no angulation compensation and gingival height range. The second reference predicate (ET SmartFit, K123627) has same manufacturing process and facility, similar dimensions but only difference is a material on the top (Zirconia vs Titanium). This proposed device is manufactured using identical material and manufacturing process to a previously cleared predicates.

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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 similar technological characteristics as the predicate device of the ET Hybrid Abutments (K162390) of Hiossen, Inc.. 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 difference is the angle of coping part.

7. Summary of nonclinical testing

The following nonclinical testing data were provided or relied upon in support of the substantial equivalence determination.

1) Biocompatibility

Hiossen, Inc predicate K162390 was relied upon for biocompatibility. The subject device is manufactured using identical materials and manufacturing processes to a previously cleared predicates identified above. 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)

2) Fatigue testing

Additional non-clinical testing data submitted to demonstrate substantial equivalence includes static and dynamic fatigue test according to ISO 14801 in saline at 2Hz on the final finished sterilized abutment.

3) Sterilization Validation

For the subject device, it is same in material(Titanium & Zirconia, Cement). This test had been conducted using worst case sample which is the longest height and the largest diameter. But only difference in between the proposed device and primary predicate device is angulation. Therefore, no additional testing is required. The steam sterilization validation for the predicate device was conducted according to ISO 17665-1, ISO/TS 17665-2 for gravity displacement on wrapped condition.

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.