Hiossen, Inc.
Peter Lee
QA/RA Manager
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

May 29, 2024

Re: K233389
Trade/Device Name: EK Digital Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 28, 2024
Received: May 28, 2024

Dear Peter Lee:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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Section 5 Indication for Use Statement – 1 PAGE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number (*if known*)

Device Name

EK Digital Abutments

Indications for Use (*Describe*)

EK DIGITAL ABUTMENTS are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Type of use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (8/23) Page 1 of 1 PSC Publishing Service (301) 443-6740 EF

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510(k) Summary

6.1 Submitter Information:

Submitted by: Hiossen, Inc.
85 Ben Fairless Drive
Fairless Hills, PA 19030

Contact Person: Peter Lee
Telephone Number: 267-759-7031
Fax Number: 267-759-7031

Date Prepared: May 29, 2024

6.2 Device Name:

- Proprietary Name: EK Digital Abutments
- Classification Name: Implant, Endosseous, Root-form
- CFR Number: 872.3630
- Device Class: Class II
- Product Code: NHA

6.3 Predicate Devices:

Primary	510(k)	Manufacturer(s)
ET SMARTFIT ABUTMENT	K123627	HIOSSEN, INC.

Reference	510(k)	Manufacturer(s)
ET HYBRID ABUTMENT	K162390	HIOSSEN, INC.
EK DENTAL IMPLANT SYSTEM	K203360	HIOSSEN, INC.

6.4 Description of Device:

EK DIGITAL ABUTMENTS are digitally designed patient specific abutments manufactured from titanium Alloy (Ti-6Al-4V ELI) and titanium alloy + zirconia. The EK Hybrid abutments are a two-piece abutment consisting of a pre-manufactured titanium base (ASTM F136) and a CAD/CAM patient-matched mesostructure component (ISO 6872) and PANAVIA F 2.0 (K032455) cement is used to attach the two structures. They are intended only for use with HIOSSEN EK dental implants to provide support for customized prosthetic restorations. EK DIGITAL ABUTMENTS are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. Each EK DIGITAL ABUTMENT is individually prescribed by the clinician.

The EK Digital Abutments are only compatible with EK Dental Implants

Propriety Name	EK Implant System
510(k) Number	K203360
Implant Diameters	3.5, 4.0, 4.5, 5.0, 5.5
Connection Type	Internal connection
Implant – Abutment Connection Type	Hex or Non-Hex

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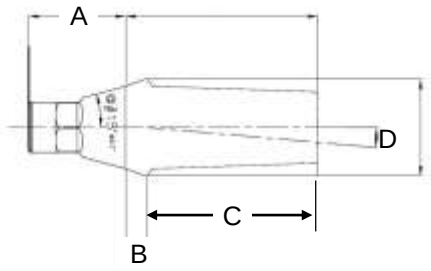
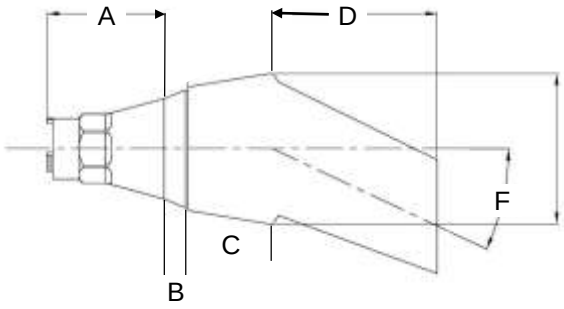
The EK Digital Abutments are available in various lengths and diameters; configurations are listed in the table below.

EK ONEFIT



Code	A (mm)	B (mm)	C (mm)	D(°)	Connection
EKCMA01H	4.0	0.5 ~ 12.0	4.0 ~ 15.5	0 ~ 10	Hex
EKCMA01N	2.6	0.5 ~ 12.0	4.0 ~ 15.5	0 ~ 10	Non-hex
EKCMA12H	4.0	0.5 ~ 12.0	4.0 ~ 15.5	10.1 ~ 20	Hex
EKCMA12N	2.6	0.5 ~ 12.0	4.0 ~ 15.5	10.1 ~ 20	Non-hex
EKCMA23H	4.0	0.5 ~ 12.0	4.0 ~ 15.5	20.1 ~ 30	Hex
EKCMA23N	2.6	0.5 ~ 12.0	4.0 ~ 15.5	20.1 ~ 30	Non-hex

EK HYBRID



Code	A (mm)	B (mm)	C (mm)	D (mm)	F (°)	Connection
EKHZA4041CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4041CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4041HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4041NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4042CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4042CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4042HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4042NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4043CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4043CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4043HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4043NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4044CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4044CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4044HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4044NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4061HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex

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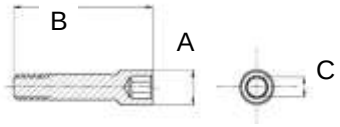
EKHZA4061NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4062HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4062NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4063HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4063NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4064HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4064NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4541CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4541CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4541HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4541NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4542CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4542CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4542HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4542NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4543CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4543CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4543HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4543NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4544CHT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4544CNT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4544HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4544NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4561HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4561NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4562HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4562NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4563HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4563NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex
EKHZA4564HT	4.0	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Hex
EKHZA4564NT	2.6	0.8 ~ 3.8	1.9 ~ 4.9	4.0 ~ 15.0	0 ~ 30	Non-hex

EK Abutment Screw



Code	A (mm)	B (mm)	C(mm)
EKABSTEP	2.12	8.7	1.20

The EK Digital Abutments are 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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6.5 Indication for Use:

EK DIGITAL ABUTMENTS are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

6.6 Substantial Equivalence:

6.6.1 EK Digital Abutments

The information and date provided in this submission established the EK Digital Abutment are substantially equivalent to the primary predicate devices listed below. The materials used, manufacturing process, design limitations are same except for the connection and compatible dental implant.

Device	**Proposed Device** **EK Digtal Abutments**	**Primary Predicate Devices** **ET Smartfit Abutment**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.
510(K) No.	K233389	K123627
Intended use	EK DIGITAL ABUTMENTS are 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.
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• PT+PE Pouch	• PT+PE Pouch
EK ONEFIT **Design**		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Design Limitations	**Connection** / **Non-hex** / **Hex** 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)*: 4~15.5(mm) / 4~15.5 (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): 0.5~8.5 (mm) / 0.5~8.5 (mm) Abutment Taper(A): 0 ~ 30 (°) / 0 ~ 30 (°) **Post height is the height above any gingival collar height.*	• Height: minimum 4.0mm above margin • Wall thickness: 0.7mm and greater • Angulation: maximum of 30°

Device	**Proposed Device** **EK Digital Abutments**	**Secondary Predicate Devices** **ET Hybrid**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.
510(K) No.	K233389	K162390
Intended use	EK DIGITAL ABUTMENTS are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	ET Hybrid Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns and bridges.
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• PT+PE Pouch	• PT+PE Pouch

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<table>
<tr><td colspan="3">EK HYBRID</td></tr>
<tr><td>Design</td><td>  </td><td>  </td></tr>
<tr><td>Surface</td><td>Machine surface</td><td>Machine surface</td></tr>
<tr><td>Material</td><td>• Titanium alloy Ti-6Al-4V (ASTM F 136)
• Zirconium oxide</td><td>• Titanium alloy Ti-6Al-4V (ASTM F 136)
• Zirconium oxide</td></tr>
<tr><td>Design Limitations</td><td>
<table>
<tr><th>Connection</th><th>Non-hex</th><th>Hex</th></tr>
<tr><td>Diameter (D)</td><td>4.2~15 (mm)</td><td>4.7~15 (mm)</td></tr>
<tr><td>Wall Thick.</td><td>0.35~0.55 (mm)</td><td>0.40~0.65 (mm)</td></tr>
<tr><td>Post Height(H)*</td><td>4~15 (mm)</td><td>4~15 (mm)</td></tr>
<tr><td>Post Wall Thick(t)</td><td>0.7~2.7 (mm)</td><td>1.2~4.2 (mm)</td></tr>
<tr><td>Post Diameter (d)</td><td>2.5~6.5 (mm)</td><td>3.0~9.0 (mm)</td></tr>
<tr><td>Ti Base Gingival Margin Height (G/H)</td><td>0.8~3.8 (mm)</td><td>0.8~3.8(mm)</td></tr>
<tr><td>Ceramic Coping Gingival Margin Height (G/H)</td><td>1.9~4.9(mm)</td><td>1.9~4.9(mm)</td></tr>
<tr><td>Abutment Taper(A)</td><td>0 ~ 30 (°)</td><td>0 ~ 30 (°)</td></tr>
</table>
*Post height is the height above any gingival collar height.</td><td>• Height: minimum 4.0mm above margin
• Wall thickness: 0.7mm and greater
• Angulation: maximum of 30°</td></tr>
</table>

6.7 Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include data from the following tests:

Biocompatibility Testing

The EK Digital Abutment are manufactured using the same manufacturing process and same well known and well-established material as the predicate device; therefore, we reason it was not necessary to re-test biocompatibility in order to support the biological safety of the EK Digital Abutment. Furthermore, as described in International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing when a new material is used that has not been identified in a primary predicate device. The proposed devices are manufactured from standard raw material that are used in the primary predicate devices and other currently marketed dental implant and abutment system. Therefore, no additional biocompatibility testing is required to establish substantial equivalence.

Sterilization Validation

The EK Digital Abutment are manufactured by the predicate device manufacturer using the same manufacturing process, material and utilizes the same packing materials) are not sterilized like the predicate devices listed in this submission. Like the predicate devices the proposed can be moist heat sterilized and was validated following ISO 17665-1 [2006] Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, therefore we reason it was not necessary to re-test validation in order to support sterilization validity of the EK Digital Abutments.

Shelf Life

The EK Digital Abutment like the predicate listed in this submission do not have a stated shelf life. The proposed devices are non-sterile and use the same exact packaging materials, manufactured from medical grade titanium alloy which are non-mechanical, non-active materials therefore, degradation in performance characteristics is not likely.

Surface Treatment Characterization Testing

The EK Digital Abutment are manufactured by the predicate device manufacturer, with surfaces using the same manufacturing process, material and surface finishing as the predicate devices listed in this submission. No additional character testing was necessary to support the equivalency of the EK Digital Abutments.

Mechanical Properties

The EK Digital Abutment System Mechanical testing was conducted in accordance to ISO 14801 Dentistry – Fatigue Test for Endosseous Dental Implants. The worst case implant and titanium abutments chosen for the tests were the smallest diameter implant loaded with abutments with the greatest angulation. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the primary predicate.

6.8 Clinical Performance Testing

No clinical performance report(s) is being submitted.

6.9 Conclusion

In accordance with the Federal Food Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, HIOSSEN, INC. concludes since the EK Digital Abutment has the same design, intended use, structure, diameters, lengths, material surface, sterilization and packaging as the predicate devices listed in this submission are substantially equivalent. The propose devices do not pose any new or increased risk as compared to both the legally marketed predicate and reference devices.