



January 8, 2025

Hiossen, Inc.  
% Ankur Naik  
Managing Director  
IZiel Healthcare  
Pentagon P1, Office No. 601 and 604 Magarpatta City,  
Hadapsar  
Pune, Maharashtra 411028  
INDIA

Re: K241003

Trade/Device Name: HIOSSSEN Pre-milled Abutment (ET Pre-milled Abutment & EK Pre-milled Abutment)

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: Class II

Product Code: NHA

Dated: December 9, 2024

Received: December 9, 2024

Dear Ankur Naik:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K241003

Device Name  
HIOSSSEN Pre-milled Abutment (ET Pre-milled Abutment & EK Pre-milled Abutment)

### Indications for Use (Describe)

The HIOSSSEN Pre-milled Abutments are intended for use with HIOSSSEN dental implants to provide support for prosthetic restorations such as crowns, bridges or overdentures.

All digitally designed CAD/CAM customizations for the HIOSSSEN Pre-milled Abutments are intended to be sent to a HIOSSSEN validated milling facility.

ET HIOSSSEN Pre-milled Abutments are compatible with the following devices:

1. ETIII & ETII SA Dental Implants (Mini, Regular, (Ultra-wide Regular) - K140934  
/ Implant Diameter (mm):3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.25, 4.63, 4.65, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8
2. ETIII NH Dental Implants (Mini & Regular, Ultra-wide Regular) - K151626  
/Implant Diameter (mm): 3.77, 3.75, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.10
3. ETIII SA D3.2 Dental Implants (Mini) - K153332  
/Implant Diameter (mm): 3.2
4. ET IV SA Dental Implants (Regular & Ultra-wide)- K183242  
/Implant Diameter (mm):4.4, 4.8, 5.25, 6.2 & 7.1

EK HIOSSSEN Pre-milled Abutments are compatible with the following devices:

1. EKIII SA Dental Implant (Mini) & EKIII NH Dental Implants (Mini) - K203360  
/Implant Diameter (mm):3.5 ~ 5.5

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## K241003 - 510(k) Summary

<b>Date:</b>	08 January 2025
<b>Submitter (Owner):</b>	Peter Lee QA/RA Manager Hiossen, Inc. 85 Ben Fairless Drive, Fairless Hills, PA 19030. P: 888-768-0001 Email: <a href="mailto:peter.l@hiossen.com">peter.l@hiossen.com</a>
<b>510(k) Contact Person:</b>	Ankur Naik Managing Director IZiel Healthcare Pentagon P1, Office No. 601 & 604, Magarpatta City, Hadapsar, Pune 411028. P: +91 72762 2555      M: +91 7069553814 Email: <a href="mailto:ankur.naik@izielhealthcare.com">ankur.naik@izielhealthcare.com</a>
<b>Device Trade Name:</b>	HIOSEN Pre-milled Abutment (ET Pre-milled Abutment & EK Pre-milled Abutment)
<b>Regulation Number:</b>	21 CFR 872.3630
<b>Review Panel:</b>	Dental
<b>Device Class:</b>	Class II
<b>Product Code:</b>	NHA
<b>Predicate Device:</b>	ET SMARTFit Abutment ( <b>K123627</b> )
<b>Reference Device:</b>	Warantec Custom Abutment ( <b>K221972</b> ) HIOSEN Implant System ( <b>K140934</b> ) ETIII Bio-SA Fixture System ( <b>K151626</b> ) ETIII SA Fixture System (Ø 3.2mm) ( <b>K153332</b> ) ET IV SA Dental Implants ( <b>K183242</b> ) EK Dental Implants and Abutments ( <b>K203360</b> )

### Device Description

HIOSEN Pre-milled Abutments are intended to support prosthetic restorations such as crowns, bridges or overdentures and used only with the Hiossen implant fixtures. HIOSEN Pre-milled Abutments are customized (Milled) as per the patient specific requirements in the Hiossen validated milling laboratory. The HIOSEN Pre-milled Abutments are designed and manufactured by Hiossen, Inc.

Model No	Model Name	Model Description
HIOSSSEN Pre-milled Abutment system	ET HIOSSSEN Pre-milled Abutments	The Hiossen Pre-milled Abutments are straight titanium abutments intended to support the prosthetic restorations such as crowns, bridges or overdentures and intended to connect to the Hiossen implant system, ETIII Nano-NH Fixture System, ETIII SA Fixture system, and ET IV SA Dental Implant System.
	EK HIOSSSEN Pre-milled Abutments	The Hiossen Pre-milled Abutments are straight titanium abutments intended to support the prosthetic restorations such as crowns, bridges or overdentures and intended to connect to the EKIII SA Dental Implants and EKIII NH Dental Implants.

The HIOSSSEN Pre-milled Abutments are Ti-6Al-4V titanium alloy (ASTM F136) cylindrical “blanks” with HIOSSSEN dental implant-specific interface (abutment to implant connection and screw channel) to be designed and milled at a HIOSSSEN validated milling facility using CAD/CAM technology to fabricate a patient-specific abutment.

The blank cylindrical HIOSSSEN Pre-milled Abutments are supplied to the Hiossen validated milling centre. Based on the design requirements provided by the dentist, the lab will design abutment using 510k cleared CAD software and blank cylinders will be milled using the CAM machine. This customized patient specific milled abutment will be sent back to the dentist for implantation into the patient after steam sterilization.

The blank cylindrical HIOSSSEN Pre-milled Abutments are available with connections where one end is connected to CAM machine and the other end is connected to the Implant fixtures as described in Figure 1. Only milling range marked in Figure 1 will be milled using the CAM Abutments according to the specification.

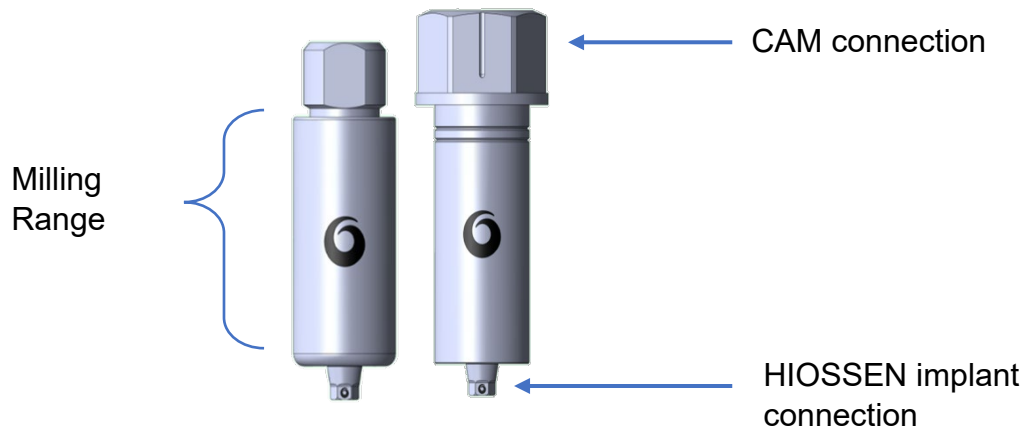


Figure 1: Illustration and Specifications

The blank cylindrical HIOSSSEN Pre-milled Abutments are designed to connect to the respective implant fixture system with hex and non-hex connection types. They are available in two connection sizes: Mini and Regular. The Mini connection size fits HIOSSSEN fixtures with diameters of 3.5 or less (3.2 & 3.5), while the Regular connection size fits HIOSSSEN fixtures with diameters of 4.0 or greater (4.0, 4.5, 5.0, 6.0, & 7.0).

ET HIOSSSEN Pre-milled Abutments are designed to connect to HIOSSSEN Implant System diameters (3.5, 4.0, 4.5, 5.0, 6.0, 7.0 mm), ETIII Nano-NH Fixture System diameters (3.5, 4.0, 4.5, 5.0, 6.0, 7.0 mm), ETIII SA Fixture System (D3.2) diameters (3.2 mm) and ET IV SA Dental Implants diameters (4.0, 4.5, 5.0, 6.0, 7.0 mm).

EK HIOSSSEN Pre-milled Abutments are designed to connect to Hiossen EKIII SA Dental Implants system diameter (3.5, 4.0, 4.5, 5.0, 5.5) and EKIII NH Dental Implant system diameter (3.5, 4.0, 4.5, 5.0, 5.5).

HIOSSSEN Pre-milled Abutments are screw-retained straight Abutments. The ET EbonyGold Screw, ET Ti Abutment Screw, and EK Ti Abutment Screw is used to retain the Abutment with the implant fixtures. The Ebony Gold Screw is made up of Titanium Alloy (ASTM F 67) which 510k cleared under K123627. EK Ti Screw is also 510k cleared under K203360.

**Specification:**

Parameters	Specification
<b>Material</b>	Titanium alloy Ti-6Al-4V (ASTM F 136)
<b>Surface</b>	Machined finished
<b>Implant abutment connection</b>	Conical
<b>Connection size</b>	Mini, Regular
<b>Connection type</b>	Hex, non-hex

Parameters	Specification
<b>Abutment design parameters</b>	Minimum wall thickness: 0.7mm Minimum gingival height: 0.5mm Minimum post height (length above the abutment collar / gingival height): 4.0mm Maximum post height (length above the abutment collar / gingival height): 17.5mm Angulation: 0° Maximum diameter: 6.8mm
<b>CAD Software</b>	510(k) cleared only
<b>Compatibility</b>	HIOSSSEN dental implants

### Intended Use / Indications for Use

The HIOSSSEN Pre-milled Abutments are intended for use with HIOSSSEN dental implants to provide support for prosthetic restorations such as crowns, bridges or overdentures. All digitally designed CAD/CAM customizations for the HIOSSSEN Pre-milled Abutments are intended to be sent to a HIOSSSEN validated milling facility.

ET HIOSSSEN Pre-milled Abutments are compatible with the following devices:

1. ETIII & ETII SA Dental Implants (Mini, Regular, (Ultra-wide Regular) - K140934 / Implant Diameter (mm):3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.25, 4.63, 4.65, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8
2. ETIII NH Dental Implants (Mini & Regular, Ultra-wide Regular) - K151626 /Implant Diameter (mm): 3.77, 3.75, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.10
3. ETIII SA D3.2 Dental Implants (Mini) - K153332 /Implant Diameter (mm): 3.2
4. ET IV SA Dental Implants (Regular & Ultra-wide)- K183242 /Implant Diameter (mm):4.4, 4.8, 5.25, 6.2 & 7.1

EK HIOSSSEN Pre-milled Abutments are compatible with the following devices:

1. EKIII SA Dental Implant (Mini) & EKIII NH Dental Implants (Mini) - K203360 /Implant Diameter (mm):3.5 ~ 5.5

## **Substantial Equivalence Discussion**

The ET SMARTFit Abutment (K123627) has been selected as the primary predicate device. Additional devices have been selected as reference devices to demonstrate the compatibility of the HIOSSEN Pre-milled Abutments with dental implant systems and include:

1. Warantec Custom Abutment - K221972
2. HIOSSEN Implant System - K140934
3. ETIII Bio-SA Fixture System - K151626
4. ETIII SA Fixture System (Ø 3.2mm) - K153332
5. ET IV SA Dental Implants - K183242
6. EK Dental Implants and Abutments - K203360

The HIOSSEN Pre-milled Abutments are milled at a "validated milling center," as specified in the indications for use. The reference device, the Warantec Custom Abutment, has been selected to support this indication.

The HIOSSEN Pre-milled Abutments are compatible with dental implant systems which are 510(k) cleared through 510(k) numbers K140934, K151626, K153332, K183242 & K203360 and are considered reference devices.

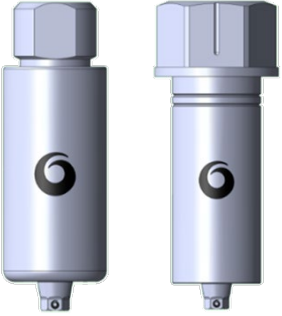

Details regarding the substantial equivalence between the subject device, the predicate device, and the reference devices are explained below.

## Technological Characteristics Comparison

**Table 1: Technological Characteristics Comparison**

Device	Subject Device	Primary Predicate Device - K123627	Reference Device – K221972	Comparison results
Product name	HIOSSSEN Pre-milled Abutments	ET SMARTFit Abutment	Warantec Custom Abutment	Not applicable
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Warantec Co., Ltd.	Not applicable
Classification name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical
Product class	Class II	Class II	Class II	Identical
Indications for use	The HIOSSSEN Pre-milled Abutments are intended for use with HIOSSSEN dental implants to provide support for prosthetic restorations such as crowns, bridges or overdentures. All digitally designed CAD/CAM customizations for the HIOSSSEN Pre-milled Abutments are intended to be sent to a HIOSSSEN validated milling facility.	ET SMARTFit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures	The Warantec dental abutment is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation.  All digitally designed abutments for use with Warantec Custom Abutments are intended to be sent to a Warantec validated milling center for manufacture.	Similar  The HIOSSSEN Pre-milled Abutments also include the compatible devices and their corresponding 510(k) numbers additionally.

Device	Subject Device	Primary Predicate Device - K123627	Reference Device – K221972	Comparison results
	<p>ET HIOSSEN Pre-milled Abutments are compatible with the following devices:</p> <p>1. ETIII &amp; ETII SA Dental Implants (Mini, Regular, (Ultra-wide Regular) - K140934</p> <p>/ Implant Diameter (mm):3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.25, 4.63, 4.65, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8</p> <p>2. ETIII NH Dental Implants (Mini &amp; Regular, Ultra-wide Regular) - K151626</p> <p>/Implant Diameter (mm): 3.77, 3.75, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.10</p> <p>3. ETIII SA D3.2 Dental Implants (Mini) - K153332</p> <p>/Implant Diameter (mm): 3.2</p> <p>4. ET IV SA Dental Implants (Regular &amp; Ultra-wide)- K183242</p>			

Device	Subject Device	Primary Predicate Device - K123627	Reference Device – K221972	Comparison results
	/Implant Diameter (mm):4.4, 4.8, 5.25, 6.2 & 7.1  EK HIOSSEN Pre-milled Abutments are compatible with the following devices: 1. EKIII SA Dental Implant (Mini) & EKIII NH Dental Implants (Mini) - K203360 /Implant Diameter (mm):3.5 ~ 5.5			
Image			-	Similar
Material	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Ti-6Al-4V ELI (ASTM F136)	Identical to predicate device.
Surface	Machined finished	Machined finished	-	Identical
Connection	Conical	Conical	-	Identical
Abutment design parameters	Minimum wall thickness: 0.7mm	Minimum wall thickness: 0.7mm	Minimum thickness: 0.4 mm	The HIOSSEN Pre-milled Abutments are straight, whereas the

Device	Subject Device	Primary Predicate Device - K123627	Reference Device – K221972	Comparison results
	Minimum gingival height: 0.5mm Minimum post height (length above the abutment collar / gingival height): 4.0m Maximum post height (length above the abutment collar / gingival height): 17.5mm Angulation: 0° Maximum diameter: 6.8mm	Minimum gingival height: 0.5mm Minimum post height: 4.0m Maximum post height: 17.5mm Maximum angulation: 30° Maximum diameter: 6.8mm	Minimum gingival height: 0.5mm Minimum post height: 4.0mm Maximum post height: 8 mm Maximum angulation: 30° Maximum diameter: 6.0mm	predicate devices are both straight and angled abutments.
Sterility	Provided non-sterile, end-user sterilization	Provided non-sterile, end-user sterilization	Provided non-sterile, end-user sterilization	Identical
Sterilization	Moist Heat	Moist Heat	Autoclave	Identical
CAD Software	510(k) cleared only	-	510(k) cleared only	Identical
Surface Treatment	None	None	None	Identical
Compatible Implants	ET HIOSSEN Pre-milled Abutments are compatible with the following device: <ul style="list-style-type: none"> <li>ETIII &amp; ETII SA Dental Implants (Mini, Regular, (Ultra-wide Regular) - K140934</li> <li>ETIII NH Dental Implants (Mini &amp;</li> </ul>	ET SMARTFit Abutment is compatible with the following device: <ul style="list-style-type: none"> <li>ETIII SA Dental Implants (Mini, Regular, (Ultra-wide Regular) - K140934</li> <li>ETIII NH Dental Implants (Mini &amp;</li> </ul>	Not available	The HIOSSEN Pre-milled Abutments are compatible with the following 510(k)-cleared dental implant systems: <ol style="list-style-type: none"> <li>HIOSSEN Implant System - K140934</li> <li>ETIII Bio-SA Fixture System - K151626</li> </ol>

Device	Subject Device	Primary Predicate Device - K123627	Reference Device – K221972	Comparison results
	<p>Regular, Ultra-wide Regular) - K151626</p> <ul style="list-style-type: none"> <li>• ETIII SA D3.2 Dental Implants (Mini) - K153332</li> <li>• ET IV SA Dental Implants (Regular &amp; Ultra-wide)- K183242</li> </ul> <p>EK HIOSSEN Pre-milled Abutments are compatible with the following device:</p> <ul style="list-style-type: none"> <li>• EKIII SA Dental Implant (Mini) &amp; EKIII NH Dental Implants (Mini) - K203360</li> </ul>	<p>Regular, Ultra-wide Regular) - K151626</p> <ul style="list-style-type: none"> <li>• ETIII SA D3.2 Dental Implants (Mini) - K153332</li> <li>• ET IV SA Dental Implants (Regular &amp; Ultra-wide)- K183242</li> </ul>		<ol style="list-style-type: none"> <li>3. ETIII SA Fixture System (Ø 3.2mm) - K153332</li> <li>4. ET IV SA Dental Implants - K183242</li> <li>5. EK Dental Implants and Abutments - K203360</li> </ol> <p>This does not raise any concern regarding the safety or performance of the device.</p>
Compatible screw	<p>ET HIOSSEN Pre-milled Abutments will be implanted either with the ET Ebony Gold Screw (K123627) or the ET Ti Screw (K123627).</p> <p>EK HIOSSEN Pre-milled Abutments will be implanted with the Ti Abutment Screw (K203360)</p>	<p>ET SMARTFit Abutment will be implanted either with the ET Ebony Gold Screw (K123627) or the ET Ti Screw (K123627).</p>	Not available	<p>Similar</p> <p>The subject device is intended to be used with screw that are already 510(k)-cleared. Therefore, this does not raise any concern regarding the safety or performance of the device.</p>

### **Discussion of similarities and differences:**

The HIOSSEN Pre-milled Abutments (including the ET Premilled Abutments and EK Premilled Abutments) are similar to the predicate device, with the only noted difference being that the HIOSSEN Pre-milled Abutments are milled at a Hiossen-validated milling facility, whereas the ET Smartfit Abutments are manufactured at the Hiossen site. However, the Hiossen-validated milling facility operates identically to the reference device's manufacturing process. Both devices use CAD/CAM technology to mill the abutments based on the technical specifications provided by the dentist. Furthermore, the Hiossen-validated milling facilities adhere to HIOSSEN's strict and stringent Quality Management System (QMS) policies. HIOSSEN performs periodic audits of these facilities and requires records of product inspections. Therefore, this difference does not raise any concern regarding the safety or performance of the device. The HIOSSEN Pre-milled Abutments are made of Titanium alloy Ti-6Al-4V (ASTM F 136), which is identical to the material used in both the predicate and reference devices. The HIOSSEN Pre-milled Abutments are compatible with 510(k)-cleared dental implant systems that are identical to the following reference devices: HIOSSEN Implant System - K140934, ETIII Bio-SA Fixture System - K151626, ETIII SA Fixture System (Ø 3.2mm) - K153332, ET IV SA Dental Implants - K183242 & EK Dental Implants and Abutments - K203360.

### **Performance data**

The HIOSSEN Pre-milled Abutments comply with the requirements of the special control documents "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments" and the products have been developed as per 21 CFR 820 and have completed design control activities, including risk management, verification, and validation.

The HIOSSEN Pre-milled Abutments complies with the following standards:

#### **Labels & IFU:**

- 1) ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.
- 2) ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices — Information to be supplied by the manufacturer.

#### **Biocompatibility:**

- 1) ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Biocompatibility testing is being leveraged from the primary predicate device – K123627 where the device was evaluated as per the above-mentioned standard.

**Sterilization:**

- 1) ISO 17665-1 First edition 2006-08-15 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- 2) ISO TS 17665-2 First edition 2009-01-15 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.
- 3) ANSI/AAMI ST79:2010, A1:2010 and A2:2011 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Sterilization validation for the primary predicate device was conducted in accordance with the aforementioned standards. Since there is no difference in the sterilization method or its parameters between the subject device and the primary predicate device, the sterilization validation data from the primary predicate device is being leveraged for the subject device.

**MR safety environment:**

Non-clinical worst-case MRI review was performed to evaluate the subject devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." *Journal of Testing and Evaluation* 4 9.2 (2 01 9): 7 8 3-795). Rationale addressed parameters per the FDA guidance "Testing and Labelling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

The non-clinical testing results demonstrate that the subject devices are substantially equivalent to the predicate devices

**Summary of Clinical Testing:**

The available non-clinical data are sufficient to support the safety and performance of HIOSSEN Pre-milled Abutments. Hence clinical studies are not required.

**Conclusion**

All the above details collectively demonstrate that HIOSSEN Pre-milled Abutments are safe and effective when the device is used as labelled and are substantially equivalent to the predicate device.