January 7, 2022

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

Re: K203360
Trade/Device Name: EK Dental Implants and Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 6, 2021
Received: December 7, 2021

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number (*if known*)
K203360

Device Name

EK Implants and Abutments System

Indications for Use (*Describe*)

The EK Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is indicated for delayed loading. Ultra wide versions are indicated for use in the molar region only.

The EK Dental Implants (Ø3.5mm) are made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The EK Dental Implants (Ø3.5mm) are indicated for use in mandibular and maxillary lateral and central incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.

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.

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510(k) Summary

6.1 Submitter Information: K203360

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: December 27, 2021

6.2 Device Name:

- Proprietary Name: EK Implants and Abutments System
- Classification Name: Endosseous dental implant
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE
- Subsequent Product Code: NHA

6.3 Predicate Devices:

Primary	510(k)	Manufacturer(s)
Hiossen Implant System	K140934	Hiossen, Inc.

Reference	510(k)	Manufacturer
ETIII Bio-SA Fixture System	K151626	Hiossen, Inc.
ETIII SA Fixture D3.2	K153332	Hiossen, Inc.
Osstem Abutment System	K182091	Osstem Implant Co., Ltd.
Osstem Implant System - Abutment	K161689	Osstem Implant Co., Ltd.
Hiossen Prosthetic System	K140507	Osstem Implant Co., Ltd.
Prosthetic System	K110308	Osstem Implant Co., Ltd.

6.4 Description of Device:

The EK Dental Implants are intended to be surgically placed in the bone of the upper or lower jaw arches, providing support to prosthetic devices to restore normal chewing functions. There are two types: SA and NH, both are bone level implants with the exact same internal hex, tapered body, use the same EK Dental Abutments, are manufactured from the same medical grade titanium materials and sterilized via gamma radiation. They only difference is the surface; SA is sand blasted and acid etched and NH which is SA + D-glucose + NaCl.

The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients. Manufactured from medical grade titanium alloy and delivered non-sterilized.

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

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EK DENTAL IMPLANTS	Diameter (mm)	Length (mm)
EKIII SA Implants	3.5	8.5, 10.0, 11.5, 13.0
	4.0 ~ 5.5	7.0, 8.5, 10.0, 11.5, 13.0
EKIII NH Implants	3.5	8.5, 10.0, 11.5, 13.0
	4.0 ~ 5.5	7.0, 8.5, 10.0, 11.5, 13.0

EK DENTAL ABUTMENTS	Diameter (mm)	Length (mm)
EK Healing	4.0 ~ 8.0	3.0 ~ 7.0
EK Angled	4.0 ~ 6.0	13.0, 15.0
EK Freeform ST	4.0 ~ 7.0	14.0, 15.0
EK Goldcast	4.0, 4.5	13.0 ~ 16.0
EK Multi	4.8	9.0 ~ 13.0
EK Multi Angled	4.8	6.0, 7.0, 8.0
EK NP Cast	4.0, 4.5	13.0 ~ 16.0
EK Rigid	4.0 ~ 7.0	4.0, 5.5, 7.0
EK Stud	3.5	9.0 ~ 15.0
EK Temporary	4.0, 4.5	13.0 ~ 16.0
EK Transfer	4.0 ~ 7.0	8.0 ~ 15.0

The EK Dental Implants and Abutments are similar to other commercially available products based on the intended use, the technology used, the material composition employed and performance characteristics.

6.5 Indication for Use:

The EK Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is indicated for delayed loading. Ultra wide versions are indicated for use in the molar region only.

The EK Dental Implants (Ø3.5mm) are made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The EK Dental Implants (Ø3.5mm) are indicated for use in mandibular and maxillary lateral and central incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.

6.6 Substantial Equivalence:

6.6.1 EK Dental Implants

The information and date provided in this submission established the EK Dental Implants are substantially equivalent to the primary predicate device, Hiossen Implant System (K140934).

Device	Proposed Devices EKIII SA Dental Implants	Primary Predicate Devices Hiossen Implant System	Reference Devices ETIII SA Fixture D3.2
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.
510(K) No.	K203360	K140934	K153332

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Design			
Intended use	The EK Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is indicated for delayed loading. Ultra wide versions are indicated for use in the molar region only. The EK Dental Implants (Ø3.5mm) are made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The EK Dental Implants (Ø3.5mm) are indicated for use in mandibular and maxillary lateral and central incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The HIOSSEN Implant 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.	The ETIII SA Fixture System (Ø3.2mm) is made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and centeral incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

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Structure	• Internal Hex-connected • Submerged Fixture • Tapered body shape	• Internal Hex-connected • Submerged Fixture • Tapered body shape & Straight body shape	• Internal Hex-connected • Submerged Fixture • Straight body shape
Diameters	3.5 ~5.5	3.5 ~ 7.0	3.2
Lengths	7.0 ~ 13.0	6.0 ~ 18.0	8.0 ~ 15.0
Material	• Pure Titanium Grade 4 (ASTM F67) • Titanium alloy Ti-6Al-4V (ASTM F136)*	• Pure Titanium Grade 4 (ASTM F67)	• Titanium alloy Ti-6Al-4V (ASTM F136)*
Surface	• SA (Sandblasted and Acid etched)	• SA (Sandblasted and Acid etched)	• SA (Sandblasted and Acid etched)
Sterilization	Gamma Radiation	Gamma Radiation	Gamma Radiation
Packaging	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.

*3.5 diameter implant only

Device	**Proposed Device** **EKIII NH Dental Implants**	**Primary Predicate Devices** **EIII Bio-SA Fixture System**	**Reference Devices** **ETIII SA Fixture D3.2**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.
510(K) No.	New device	K151626	K153332
Design			
Intended use	The EK Dental Implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented, screw or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is indicated for delayed loading. Ultra wide versions are indicated for use in the molar region only. The EK Dental Implants (Ø3.5mm) are made of titanium alloy (Ti 6Al 4V)	The ETIII Bio-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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Fixture System is intended to be used in the molar region.	The ETIII SA Fixture System (Ø3.2mm) is made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure titanium for Cover Screw. The ETIII SA Fixture System (Ø3.2mm) is indicated for use in mandibular and maxillary lateral and centeral incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

	for Fixtures and Simple Mount and pure titanium for Cover Screw. The EK Dental Implants (Ø3.5mm) are indicated for use in mandibular and maxillary lateral and central incisor, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.		
Structure	• Internal Hex-connected • Submerged Fixture • Tapered body shape	• Internal Hex-connected • Submerged Fixture • Tapered body shape	• Internal Hex-connected • Submerged Fixture • Straight body shape
Diameters	3.5 ~ 5.5	3.5 ~ 7.0	3.2
Lengths	7.0 ~ 13.0	6.0 ~ 15.0	8.0 ~ 15.0
Material	• Pure Titanium Grade 4 (ASTM F67) • Titanium alloy Ti-6Al-4V (ASTM F136)*	• Pure Titanium Grade 4 (ASTM F67)	• Titanium alloy Ti-6Al-4V (ASTM F136)*
Surface	• NH (SA + D-glucose + NaCl)	• NH (SA + D-glucose + NaCl)	• NH (SA + D-glucose + NaCl)**
Sterilization	Gamma Radiation	Gamma Radiation	Gamma Radiation
Packaging	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.

* 3.5 diameter implant only
** NH version was adopted via internal documentation (letter to file).

Device	**Proposed Device EK Healing Abutment**	**Reference Devices Hiossen Healing Abutment**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.
510(K) No.	New device	K140934

Design		
Intended use	Used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.	Used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.
Diameters	4.0 ~ 8.0	4.0 ~ 8.0
Lengths	3.0 ~ 7.0	3.0 ~ 7.0
Material	• Pure Titanium Grade 4 (ASTM F67)	• Pure Titanium Grade 4 (ASTM F67)
Surface	• Machine surface	• Machine surface
Sterilization	• Gamma Radiation	• Gamma Radiation
Packaging	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.

6.6.2 EK Dental Abutments

The information and date provided in this submission established the EK Dental Implants are substantially equivalent to the reference devices listed below.

Device	**Proposed Device EK Dental Abutments**	**Reference Devices Osstem Abutment System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K182091
Intended use	The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The Osstem Abutments System are indicated for use with Hiossen Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.
ANGLED Design		
Diameters(mm)	4.0 ~ 6.0	4.0 ~ 6.0
Heights(mm)	8.0	8.0
Angulation	17°	17°

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MULTI ANGLED Design		
Diameters(mm)	4.8	4.8
G/H(mm)	2.5 ~ 5.0	2.5 ~ 5.0
Angulation	17°	17°, 30°
STUD Design		
Diameters(mm)	3.5	3.5
G/H(mm)	1.0 ~ 6.0	1.0 ~ 6.0
TEMPORARY Design		
Diameters(mm)	4.0, 4.5	4.0, 4.5
Height(mm)	10	10
TRANSFER Design		
Diameters(mm)	4.0 ~ 7.0	4.0 ~ 7.0
Height(mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0

Device	**Proposed Device EK Dental Abutments**	**Reference Devices Osstem Implant System - Abutment**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K161689
Intended use	The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The Osstem Implant System - Abutments are indicated for use with Hiossen Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• Secured in plastic ampule	• Secured in plastic ampule

	• Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.
FREEFORM ST Design		
Diameters(mm)	4.0 ~ 7.0	4.0 ~ 7.0
G/H(mm)	1.5, 3.0	1.5, 3.0
MULTI Design		
Diameters(mm)	4.8	4.8
G/H(mm)	1.0 ~ 5.0	1.0 ~ 5.0
RIGID Design		
Diameters(mm)	4.0 ~ 7.0	4.0 ~ 7.0
Height(mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0

Device	**Proposed Device EK Dental Abutments**	**Reference Devices Hiossen Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K140507
Intended use	The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The Hiossen Prosthetic System are indicated for use with Hiossen Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.
Material	• Co-Cr-Mo Alloy	• Co-Cr-Mo Alloy
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.
NP CAST Design		

Diameters(mm)	4.0, 4.5	4.0, 4.5
Height(mm)	10	10
Design parameters	• Height: minimum 4.0mmm above margin • Wall thickness: 0.7mm and greater • Angulation: maximum of 30 degrees	• Height: minimum 4.0mmm above margin • Wall thickness: 0.7mm and greater • Angulation: maximum of 30 degrees

Device	**Proposed Device** **EK Dental Abutments**	**Reference Devices** **Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K110308
Intended use	The EK Dental Abutments are indicated for use with EK Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The Prosthetic System are indicated for use with Hiossen Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.
Material	• Gold alloy	• Gold alloy
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user
Packaging	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.
GOLD CAST Design		
Diameters(mm)	4.0, 4.5	4.0, 4.5
Height(mm)	10	10
Design parameters	• Height: minimum 4.0mmm above margin • Wall thickness: 0.7mm and greater • Angulation: maximum of 30 degrees	• Height: minimum 4.0mmm above margin • Wall thickness: 0.7mm and greater • Angulation: maximum of 30 degrees

6.7 Non-Clinical Performance Data

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

Biocompatibility Testing

The EK Dental Implants and Abutments are manufactured using the same manufacturing process and same well known and well established material as the predicate and reference devices, therefore we reason it was not necessary to re-test biocompatibility in order to support the biological safety of the EK Dental Implant and Abutments.

Sterilization Validation

The EK Dental Implants and healing abutments are gamma irradiated under the same conditions and process as the predicate device, the Hiossen Implant System (K140934) and validated following ISO 11137 [2006] Sterilization of health care products – Requirements for Validation and Routine control – Radiation Sterilization guidelines, therefore we reason it was not necessary to re-test validation in order to support

the sterilization validity of the EK Dental Implants & healing abutments and includes acceptance of prior LAL endotoxin testing information from prior clearance.

EK Dental Abutments are provided non-sterile and can be moist heat sterilized as the reference devices, K182091, K161689, K140507 and K110308 which 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 Dental Abutments.

Shelf Life
The EK Dental Implants shelf life are identical to the predicate device HIOSSEN Implant System (K140934) which has been validated for eight (8) years following ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems. The EK Dental Implants utilizes the exact same packaging materials & methods and is a medical grade titanium, nonmechanical, non-active device, therefore, degradation in performance characteristics is not likely over the established shelf life period. Therefore, no shelf-life re-validation or accelerated aging re-testing was performed.

EK Dental Abutments 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 nonmechanical, non-active materials therefore, degradation in performance characteristics is not likely.

Surface Treatment Characterization Testing
The EK Dental Implants surfaces are manufactured using the same manufacturing process, material and is its surface is SA & NH treated just as the predicate device, the Hiossen Implant System (K140934) & ETIII SA Fixture D3.2 and coated SA treated ETIII Bio-SA Fixture System (K151626), therefore no additional surface characterization testing was necessary to support the equivalency of the EK Dental Implants.

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

Fatigue Testing
Mechanical testing of EK Dental Implants and Abutments in accordance to ISO 14801 Dentistry – Fatigue Test for Endosseous Dental Implants was conducted. The worst case implant and titanium, gold alloy and Co-Cr alloy 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 Dental Implant has the intended use, structure, material, surface, sterilization and packaging as the predicate device, Hiossen Implant System (K140934) and EK Dental Abutments 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.