September 12, 2024

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

Re: K240232
Trade/Device Name: EK D3.3 and Ultra Wide Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 26, 2024
Received: August 13, 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.

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) 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

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.

Submission Number *(if known)*

K240232

Device Name

EK D3.3 and Ultra Wide Dental Implants

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 & Ø3.3mm) 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 & Ø3.3mm) 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.

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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510(k) Summary

Submitter Information: K240232

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: September 12, 2024

Device Name:

- Proprietary Name: EK D3.3 and Ultra Wide Dental Implants
- Classification Name: Endosseous dental implant
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE

Predicate Devices:

Primary	510(k)	Manufacturer(s)
EK Dental Implants and Abutments System	K203360	Hiossen, Inc.

Reference	510(k)	Manufacturer(s)
Hiossen Implant System*	K140934	Hiossen, Inc.
ETIII Bio-SA Fixture System	K151626	Hiossen, Inc.
ETIII SA Fixture D3.2	K153332	Hiossen, Inc.

Description of Device:

The EK D3.3 and Ultra Wide 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 components and prosthetic parts, 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 is sand blasted and acid etched plus treated with a layer of low crystalline HA and super hydrophilic coating.

The EK D3.3 and Ultra Wide Dental Implants are available in various lengths and diameters; configurations are listed in the table below.

EK DENTAL IMPLANTS	Diameter (mm)	Length (mm)
EKIII SA D3.3 Implants	3.3	8.7, 10.2, 11.7, 13.2
EKIII SA Ultra Wide Implants	5.92	11.2, 12.7
	5.95	6.4, 9.7
	6.0	7.2, 8.2
	6.8	6.4, 7.2, 8.2, 9.7, 11.2, 12.7

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EKIII NH D3.3 Implants	3.3	8.7, 10.2, 11.7, 13.2
EKIII NH Ultra Wide Implants	5.92	11.2, 12.7
	5.95	6.4, 9.7
	6.0	7.2, 8.2
	6.8	6.4, 7.2, 8.2, 9.7, 11.2, 12.7

The EK D3.3 and Ultra Wide Dental Implants are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

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 & Ø3.3mm) 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 & Ø3.3mm) 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.

Substantial Equivalence:

The EK D3.3 and Ultra Wide Dental Implants
The information and data provided in this submission established the EK D3.3 and Ultra Wide Dental Implants are substantially equivalent to the primary predicate devices, EK Dental Implant (K203360).

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Device	Proposed Devices EK SA D3.3 and Ultra Wide Dental Implants	Predicate Devices EKIII SA Dental Implants	Reference Devices Hiossen Implant System	Reference Devices ETIII SA Fixture D3.2	Similarities/ Differences
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.	
510(K) No.	New device	K203360	K140934	K153332	
Design					Similar Difference: Size addition. Does not pose any new or increased risk.
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 & Ø3.3mm) are made of titanium alloy (Ti 6Al 4V) for Fixtures and Simple Mount and pure	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	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 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.	Similar Difference: To specify that the restriction of the 3.3mm diameter implant bodies to the lateral incisors which is covered in the indications of the K153332 submission

	titanium for Cover Screw. The EK Dental Implants (Ø3.5mm & Ø3.3mm) 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.	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 • Tapered body shape & Straight body shape	• Internal Hex-connected • Submerged Fixture • Straight body shape	Similar Difference: Size addition. Does not pose any new or increased risk.
Diameters(mm)	3.3, 5.92, 5.95, 6.0, 6.80	3.5 ~ 5.5	3.5 ~ 7.0	3.2	Equivalent

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Lengths(mm)	6.4, 7.2, 8.2, 8.7, 9.7, 10.2, 11.2, 11.7, 12.7, 13.2	7.0 ~ 13.0	6.0 ~ 18.0	8.0 ~ 15.0	Equivalent
Diameter x Length(mm)	3.3 x 8.7, 10.2, 11.7, 13.2 5.92 x 11.2, 12.7 5.95 x 6.4, 9.7 6.0 x 7.2, 9.7 6.8 x 6.4, 7.2, 8.2, 9.7, 11.2, 12.7	3.5 x 8.0 ~ 13.0 4.0 ~ 5.5 x 7.0 ~ 13.0	3.5 x 8.0 ~ 18.0 4.0 ~ 4.5 x 7.0 ~ 18.0 5.0 x 6.0 ~ 18.0 7.0 ~ 6.0 x 6.0 ~ 13.0	3.2 x 8.0 ~ 15.0	Similar Difference: Size addition. Does not pose any new or increased risk.
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)	• Pure Titanium Grade 4 (ASTM F67)	• Titanium alloy Ti-6Al-4V (ASTM F136)*	Equivalent
Surface	• SA (Sandblasted and Acid etched)	• SA (Sandblasted and Acid etched)	• SA (Sandblasted and Acid etched)	• SA (Sandblasted and Acid etched)	Equivalent
Sterilization	Gamma Radiation	Gamma Radiation	Gamma Radiation	Gamma Radiation	Equivalent
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.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	Equivalent
Shelf life	8 years	8 years	8 years	8 years	Equivalent

*3.3 diameter implant only

Device	**Proposed Device EK NH D3.3 and Ultra Wide Dental Implants**	**Proposed Device EKIII NH Dental Implants**	**Predicate Devices EIII Bio-SA Fixture System**	**Predicate Devices ETIII SA Fixture D3.2**	**Similarities/ Differences**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.	Hiossen, Inc.	
510(K) No.	New device	K203360	K151626	K153332	

Design					Similar Difference: Size addition. Does not pose any new or increased risk.
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 & Ø3.3mm) 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 & Ø3.3mm) are indicated for use in mandibular and maxillary lateral and central incisor, in	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	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.	Similar Difference: To specify that the restriction of the 3.3mm diameter implant bodies to the lateral incisors which is covered in the indications of the K153332 submission

	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.	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 • Tapered body shape	• Internal Hex-connected • Submerged Fixture • Straight body shape	Similar Difference: Size addition. Does not pose any new or increased risk.
Diameters(mm)	3.3, 5.92, 5.95, 6.0, 6.80	3.5 ~ 5.5	3.5 ~ 7.0	3.2	Equivalent
Lengths(mm)	6.4, 7.2, 8.2, 8.7, 9.7, 10.2, 11.2, 11.7, 12.7, 13.2	7.0 ~ 13.0	6.0 ~ 15.0	8.0 ~ 15.0	Equivalent
Diameter x Length(mm)	3.3 x 8.7, 10.2, 11.7, 13.2 5.92 x 11.2, 12.7 5.95 x 6.4, 9.7	3.5 x 8.0 ~ 13.0 4.0 ~ 5.5 x 7.0 ~ 13.0	3.5 x 8.0 ~ 18.0 4.0 ~ 4.5 x 7.0 ~ 18.0 5.0 x 6.0 ~ 18.0 7.0 ~ 6.0 x 6.0 ~ 13.0	3.2 x 8.0 ~ 15.0	Similar Difference: Size addition. Does

	6.0 x 7.2, 9.7 6.8 x 6.4, 7.2, 8.2, 9.7, 11.2, 12.7				not pose any new or increased risk.
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)	• Pure Titanium Grade 4 (ASTM F67)	• Titanium alloy Ti-6Al-4V (ASTM F136)*	Equivalent
Surface	• NH (Sand blased and Acid etched + nano calcium phosphate + D-glucose + NaCl)	• NH (Sand blased and Acid etched + nano calcium phosphate + D-glucose + NaCl)	• NH (Sand blased and Acid etched + nano calcium phosphate + D-glucose + NaCl)	• SA (Sand blasted and acid etched)	Equivalent
Sterilization	Gamma Radiation	Gamma Radiation	Gamma Radiation	Gamma Radiation	Equivalent
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.	• Secured in plastic ampule • Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	Equivalent
Shelf life	5 years	5 years	5 years	5 years	Equivalent

*3.3 diameter implant only

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 D3.3 and Ultra Wide Dental Implants are manufactured using the same manufacturing process and same well known and well-established material as the predicate devices; therefore, we reason it was not necessary to re-test biocompatibility in order to support the biological safety of the EK D3.3 and Ultra Wide Dental Implants as well as leveraging K203360's biocompatibility assessment. 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 D3.3 and Ultra Wide Dental Implants (manufactured using the same manufacturing process, material and utilizes the same sterilize barrier system) are gamma irradiated under the same conditions and process as the predicate devices, the EK Dental Implants and Abutments (K203360), Hiossen Implant System (K140934), ETIII Bio-SA Fixture System (K151626) & ETIII SA Fixture D3.2 (K153332) 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 D3.3 and Ultra Wide Dental Implants.

Shelf Life

The EK D3.3 and Ultra Wide Dental Implants shelf life are identical to the predicate device EK SA Dental Implants (K203360), HIOSSEN Implant System (K140934) & ETIII SA Fixture D3.2 which has been validated for eight (8) years and EK NH Dental Implants (K203360), ETIII Bio-SA Fixture System (K151626) which has been validated for five (5) years following ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems. The EK D3.3 and Ultra Wide Dental Implants utilizes the exact same packaging materials & methods and is a medical grade titanium, non-mechanical, 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.

Surface Treatment Characterization Testing

The EK D3.3 and Ultra Wide Dental Implants surfaces are manufactured using the same manufacturing process, material and its surface is SA treated type just as the predicate device, the EK SA Dental Implants (K203360), Hiossen Implant System (K140934) & ETIII SA Fixture D3.2 and NH treated type just as the predicate device EK NH Dental Implants (K203360) & ETIII Bio-SA Fixture System (K151626). The surface area analysis and bone-in-contact testing for the wide diameter implants are referenced from K140934 and state no changes in design was made that might affect surface area and bone-in-contact analysis, therefore no additional character testing was necessary to support the equivalency of the EK D3.3 and Ultra Wide Dental Implants.

Fatigue Testing

The EK D3.3 and Ultra Wide Dental Implants are manufactured using the same manufacturing process, material and same design, as the predicate EK Dental Implants (K203360). Fatigue testing performed in accordance with ISO 14801 Dentistry – Fatigue Test for Endosseous Dental Implants. The data provided in the submission demonstrates substantial equivalence.

MR conditional
Non-clinical worst-case MRI review was performed to evaluate Hiossen, Inc. EK D3.3 and Ultra Wide Dental Implants in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., 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 49.2 (2019): 783-795)., based on the entire system including all variations (all compatible implant bodied, dental abutments and, fixation screws) and material composition. Rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Clinical Performance Testing
No clinical performance report(s) is being submitted.

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 D3.3 and Ultra Wide Dental Implants has the same design, intended use, structure, diameters, lengths, material, surface, sterilization and packaging as the predicate devices, EK Dental Implants (K203360), Hiossen Implant System (K140934), ETIII Bio-SA Fixture System (K151626) & ETIII SA Fixture D3.2. The propose devices do not pose any new or increased risk as compared to both the legally marketed predicate and reference devices.