April 28, 2023

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

Re: K222636
Trade/Device Name: ET Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 30, 2023
Received: April 3, 2023

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 -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: 06/30/2023
See PRA Statement below.

510(k) Number (*if known*)
K222636

Device Name

ET Abutment System

Indications for Use (*Describe*)

The ET Abutments are indicated for use with ET 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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Section 6 510(k) Summary – 12 PAGES

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:	April 28, 2023

6.2 Device Name:

• Proprietary Name:	ET Abutment System
• 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)
Osstem Abutment System	K182091	Osstem Implant Co., Ltd.

Reference	510(k)	Manufacturer(s)
Osstem Implant System - Abutment	K161689	Osstem Implant Co., Ltd.
ET US SS Prosthetic System	K160670	Osstem Implant Co., Ltd.
Hiossen Prosthetic System	K140507	Osstem Implant Co., Ltd.
ET/SS Implant System	K120847	Osstem Implant Co., Ltd.
Prosthetic System	K110308	Osstem Implant Co., Ltd.
HS/HG Prosthetic System	K100245	Osstem Implant Co., Ltd.
HU/HS/HG Prosthetic System	K081575	Osstem Implant Co., Ltd.
US/SS/GS System	K073247	Osstem Implant Co., Ltd.
US System	K062030	Osstem Implant Co. Ltd.

6.4 Description of Device:

The ET Abutment System are indicated for use with ET 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 ET Abutments are available in various lengths and diameters; configurations are listed in the table below.

EK DENTAL ABUTMENTS	Diameter (mm)	Length (mm)
ET Angled	4.0 ~ 6.0	13.0, 15.0
ET Convertible Angled Cylinder	4.0, 4.8, 6.0	7.5
ET Goldcast	4.0, 4.5	13.0 ~ 16.0

ET Multi Angled	4.80	9.00 ~ 13.00
ET Multi Combination Cylinder	5.00	7.30
ET O-ring	3.50, 4.60	1.15, 1.50
ET Retainer, Retainer Cap	5.00	4.40
ET Port	3.70	7.00 ~ 13.00
ET Male Cap	5.50	2.25
ET Males	4.75	1.80
ET Stud	3.50	9.00 ~ 15.00
ET Temporary	4.00, 4.50	13.00 ~ 16.00
ET Transfer	4.00 ~ 7.00	8.00 ~ 15.00
ET Freeform ST	4.00 ~ 7.00	14.00, 15.00
ET Rigid	4.00 ~ 7.00	4.00, 5.50, 7.00
ET Rigid Protect Cap	4.00 ~ 7.00	4.00, 5.50, 7.00
ET Esthetic Low Temporary Cylinder	4.80, 5.30	12.00
ET Multi	4.80	9.00 ~ 13.00
ET Esthetic Low Gold Cylinder	4.80	12.00
ET Convertible Combination Cylinder	4.00, 4.80, 6.00	7.00
ET Convertible Temporary Cylinder	4.00, 4.80, 6.00	9.80
ET Convertible	4.00, 4.80, 6.00	6.00 ~ 11.00
ET Convertible GoldCast Cylinder	4.00, 4.80, 6.00	11.75, 12.15
ET Convertible Plastic Cylinder	4.00, 4.80, 6.00	12.00
ET Convertible Protect Cap	4.00, 4.80, 6.00	2.90, 3.50
ET Esthetic Low Plastic Cylinder	4.80	12.00
ET Esthetic Low Healing Cap	4.80	4.60

The ET Abutment System are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

6.5 Indication for Use:

The ET Abutment System are indicated for use with ET 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 ET Abutment System

The information and date provided in this submission established the ET Abutment System are substantially equivalent to the primary predicate devices listed below. Proposed devices are the same devices Osstem (FEI 3003394081) received clearance listed as predicate and reference devices.

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Device	Proposed Device ET Abutment System	Primary Predicate Devices Osstem Abutment System
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K182091
Intended use	The ET Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. • Link Abutment for CEREC The Link Abutment for CEREC is titanium alloy abutments placed onto OSSTEM dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.
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.
ET ANGLED		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Diameters(mm)	4.0 ~ 6.0	4.0 ~ 6.0
Heights(mm)	8.0	8.0
Angulation	17°	17°
ET CONVERTIBLE ANGLED CYLINDER		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
Diameters(mm)	4.0, 5.0	4.0, 5.0, 6.0
Height(mm)	8.0	8.0

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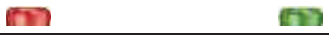
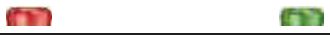
ET MULTI ANGLED		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Diameters(mm)	4.8	4.8
G/H(mm)	2.5 ~ 5.0	2.5 ~ 5.0
Angulation	17°, 30°	17°, 30°
ET MULTI COMBO CYLINDER		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
Diameters(mm)	5.0	5.0
Height(mm)	7.3	7.3
ET PORT		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Diameters(mm)	3.7	3.7
G/H(mm)	1.0 ~ 5.0	1.0 ~ 5.0
ET Male Cap		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
Diameters(mm)	5.5	5.5
Height(mm)	2.25	2.25
ET Port Males		
Design		
Material	• Nylon	• Nylon
Diameters(mm)	4.73	4.73
Height(mm)	1.80	1.80
ET Port Extended Males		
Design		
Material	• Nylon	• Nylon
Diameters(mm)	4.75	4.75
Height(mm)	1.80	1.80
ET STUD		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)

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Diameters(mm)	3.5	3.5
G/H(mm)	1.0 ~ 6.0	1.0 ~ 6.0
ET O-RING		
Design		
Material	• Acrylonitrile & Butadiene Polymer (NBR)	• Acrylonitrile & Butadiene Polymer (NBR)
Diameter	3.50, 4.60	3.50, 4.60
Height	1.15, 1.50	1.15, 1.50
ET RETAINER, CAP		
Design	 	 
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
Diameter	5.00	5.00
Height	2.00, 3.90	2.00, 3.90
ET TEMPORARY		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
Diameters(mm)	4.0, 4.5	4.0, 4.5
Height(mm)	10	10
ET TRANSFER		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136)	• Titanium alloy Ti-6Al-4V (ASTM F136)
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 ET Abutment System**	**Reference Devices Osstem Implant System - Abutment**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K161689
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The OSSTEM Implant System – 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	• 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.
ET FREEFORM ST		

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Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Max. Angulation	17°	17°
Diameters(mm)	4.0 ~ 7.0	4.0 ~ 7.0
G/H(mm)	1.5, 3.0	1.5, 3.0
ET RIGID		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Diameters(mm)	4.0 ~ 7.0	4.0 ~ 7.0
Height(mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0
ET RIGID PROTECT CAP		
Design		
Material	• PolyCarbonate Polymer	• PolyCarbonate Polymer
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** **ET Abutment System**	**Reference Devices** **ET US SS Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K160670
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	ET System The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic such as crowns, bridges, or overdentures. US/SS System The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic such as crowns, bridges, or overdentures.
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.
ET ESTHETIC LOW TEMPORARY		
Design		
Surface	Machine surface	Machine surface

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Material	• Titanium CP Grade 3	• Titanium CP Grade 3
Diameters(mm)	5.3, 4.8	5.3, 4.8
Height(mm)	12.0	12.0
ET MULTI		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Diameters(mm)	4.8	4.8
G/H(mm)	1.0 ~ 5.0	1.0 ~ 5.0

Device	**Proposed Device** **ET Abutment System**	**Reference Devices** **Hiossen Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K140507
Intended use	The ET Dental Abutments are indicated for use with ET 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 a dental implant to provide support to prosthetic restoration such as crowns, bridges and overdentures.
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.
ET ESTHETIC LOW GOLD CYLINDER		
Design		
Max. Angulation	0°	0°
Diameters(mm)	4.8	4.8
Height(mm)	12.0	12.0

Device	**Proposed Device** **ET Abutment System**	**Reference Devices** **ET/SS Implant System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K120847
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The ET/SS 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. The abutment is intended for use with a dental implant

		fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
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.
ET CONVERTIBLE COMBO CYLINDER		
Design		
Diameters(mm)	4.0, 5.0, 6.0	4.0, 5.0, 6.0
Height(mm)	7.0	7.0

Device	**Proposed Device** **ET Abutment System**	**Reference Devices** **ET/SS Implant System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K110308
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	Prosthetic System 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	• 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.
ET GOLDCAST		
Design		
Max. Angulation	30°	30°
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F136) • POM	• Titanium alloy Ti-6Al-4V (ASTM F136) • POM
Diameters(mm)	4.0, 4.5	4.0, 4.5

Device	**Proposed Device** **ET Abutment System**	**Reference Devices** **HS/HG Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K100245

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Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	HS/HG Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
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.
ET CONVERTIBLE TEMPORARY CYLINDER		
Design		
Diameters(mm)	4.0, 5.0, 6.0	4.0, 5.0, 6.0
Height(mm)	12.0	12.0

Device	**Proposed Device** **ET Abutment System**	**Reference Devices** **HU/HS/HG Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K081575
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	HU/HS/HG Prosthetic System 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	• 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.
ET CONVERTIBLE		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Diameters(mm)	4.0, 4.5	4.0, 4.5
G/H(mm)	1.0, 3.0	1.0, 3.0
ET CONVERTIBLE GOLDCAST		
Design		
Material	• Gold alloy	• Gold alloy
Max. Angulation	0°	0°

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Diameters(mm)	4.0, 4.8, 6.0	4.0, 4.8, 6.0
G/H(mm)	11.75, 12.15	11.75, 12.15
ET CONVERTIBLE PLASTIC		
Design		
Material	• Polyoxymethylene (POM)	• Polyoxymethylene (POM)
Max. Angulation	0°	0°
Diameters(mm)	4.0, 5.0, 6.0	4.0, 5.0, 6.0
G/H(mm)	12.0	12.0
ET CONVERTIBLE PROTECT CAP		
Design		
Surface	Machine surface	Machine surface
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)
Diameters(mm)	4.0, 4.8, 6.0	4.0, 4.8, 6.0
Height(mm)	2.9, 3.5	2.9, 3.5

Device	**Proposed Device ET Abutment System**	**Reference Devices US/SS/GS Prosthetic System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K073247
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	The US/SS/GS 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 terminal or intermediate abutment support for fixed bridgework. The US/SS/GS System is for single and two stage surgical procedures. It is not for immediate load..
Material	• Polyoxymethylene (POM)	• Polyoxymethylene (POM)
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.
ET ESTHETIC LOW PLASTIC CYLINDER		
Design		
Max. Angulation	0°	0°
Diameters(mm)	4.80	4.80
G/H(mm)	12.00	12.00

Device	**Proposed Device ET Abutment System**	**Reference Devices US System**

85 Ben Fairless Drive
Fairless Hills, PA 19030
888-768-0001
www.hiossen.com

Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K062030
Intended use	The ET Dental Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.	US System and SSII mini are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations, and terminal or intermediate abutment support for fixed bridgework. US System is for two stage surgical procedures. It is not for one stage or immediate load. SSII mini is for one and two stage surgical procedures. It is not for immediate load.
Surface	Machine surface	Machine surface
Material	• Titanium CP Grade 3	• Titanium CP Grade 3
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.
ET ESTHETIC LOW HEALING		
Design		
Diameters(mm)	4.80	4.80
G/H(mm)	4.60	4.60

Device	**Proposed Device ET Abutment System**	**Reference Devices US System**
Manufacturer	Hiossen, Inc.	Osstem Co., Ltd.
510(K) No.	New device	K182091
Device Description	Screw securing abutment to dental implant	Screw securing abutment to dental implant
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 • 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.
EBONY GOLD SCREW		
Design		

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 ET Abutment System are contract manufactured by the predicate device manufacturer 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 ET Abutment System. The proposed devices are manufactured from standard raw material that are used in the primary predicate device and other currently marketed dental implant and abutment system. Therefore, no additional biocompatibility testing is required to establish substantial equivalence.

Sterilization Validation
The ET Abutment System (are contract manufactured by the predicate device manufacturer using the same manufacturing process, material and utilizes the same packing materials) are 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 ET Abutment System.

Shelf Life
The ET Abutment System 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 ET Abutment System are contract 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 ET Abutment System.

Mechanical Properties
The ET Abutment System fatigue testing of the worst case scenario was conducted per Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments. Proposed dental attachments are contract manufactured by the predicate device manufacturer using the same manufacturing process, material and same design, as the predicates listed in this submission which were fatigue tested in accordance with ISO 14801 Dentistry – Fatigue Test for Endosseous Dental Implants.

MRI Compatibility
K221684 has cleared the contract manufacturer's support for the MRI compatibility of the ET Abutment System. This clearance indicates that a non-clinical worst-case MRI review was performed to evaluate the Subject device components 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 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, 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.

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 ET Abutment System 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.