May 14, 2026

Hiossen Inc
Simyung Park
Regulatory Affairs Specialist
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K253372
Trade/Device Name: ET Healing Abutments; ET Scan Healing Abutments; EK Scan Healing Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 22, 2026
Received: April 22, 2026

Dear Mateusz Leszczak:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K253372

Device Name
ET Healing Abutments;
ET Scan Healing Abutments;
EK Scan Healing Abutments

Indications for Use *(Describe)*
ET Healing Abutments, ET Scan Healing Abutments and EK Scan Healing Abutments are temporary abutments used to make a natural soft tissue shape until setting up prosthesis.

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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Traditional 510(K) Summary

Submitter Information:
Submitted by: Hiossen, Inc.
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Fairless Hills, PA 19030

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Manager, Regulatory Affairs
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Date Prepared: May 11, 2026

Device Information:
- Proprietary Name: ET Healing Abutment; ET Scan Healing Abutment; EK Scan Healing Abutment
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: Class II
- Product Code: NHA

Predicate Devices:

Primary Predicate Device	**510(k)**	**Manufacturer(s)**
Hiossen Implant System	K140934	Hiossen, Inc.
Reference Device	**510(k)**	**Manufacturer(s)**
TS Abutment System	K233194	Osstem Implant Co., Ltd.
Osstem Implant System	K222778	Osstem Implant Co, Ltd.
EK Dental Implants and Abutments	K203360	Hiossen, Inc.

Description of Device:

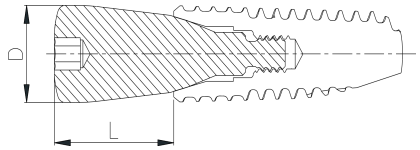
The ET Healing abutment is a temporary abutment designed for use in combination with the ET dental implant system during the healing phase following implant placement. Its primary purpose is to guide and contour the peri-implant soft tissue to create an optimal emergence profile for the final prosthetic restoration.

The ET Scan Healing abutment is designed for compatibility with Hiossen's ET Dental Implant System and combines the functionality of a healing abutment and a scan body, allowing for digital impressions to

be taken without removing the healing abutment. The Scan Healing Abutment features a unique shape on its upper surface which is captured through the use of an intraoral scanner to aid in identification within CAD programs. ET Scan Healing Abutments are available in various lengths and widths as presented within this submission.

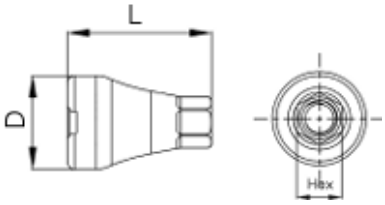
The EK Scan Healing abutment is designed for compatibility with Hiossen's EK Dental Implant System and combines the functionality of a healing abutment and a scan body, allowing for digital impressions to be taken without removing the healing abutment. The Scan Healing Abutment features a unique shape on its upper surface which is captured through the use of an intraoral scanner to aid in identification within CAD programs. EK Scan Healing Abutments are available in various lengths and widths as presented within this submission.

ET Healing Abutment

Cross-Sectional View of Implant and Healing Abutment Assembly			
ET Healing Abutment Type	**Diameter (D, mm)**	**Length (L, mm)**	**Product Code**
Mini (Anodized Yellow)	4.3	6.0	ETHLA4006M
		9.0	ETHLA4009M
	4.8	6.0	ETHLA4506M
		9.0	ETHLA4509M
Regular	4.3	6.0	ETHLA4006R
		9.0	ETHLA4009R
	4.8	6.0	ETHLA4506R
		9.0	ETHLA4509R
	5.3	6.0	ETHLA5006R

		9.0	ETHLA5009 R
	6.3	6.0	ETHLA6006 R
		9.0	ETHLA6009 R
	7.3	6.0	ETHLA7006 R
		9.0	ETHLA7009 R

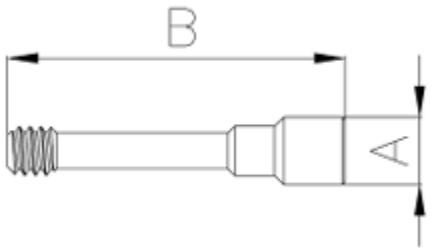
ET Scan Healing Abutment



No	Code	D (Ø)	L(mm)	Hex (mm)	Remark
1	ETSHA404MB	4.3	6.6	2.08	Mini
2	ETSHA405MB	4.3	7.6	2.08	Mini
3	ETSHA407MB	4.3	9.6	2.08	Mini
4	ETSHA409MB	4.3	11.6	2.08	Mini
5	ETSHA454MB	4.8	6.6	2.08	Mini
6	ETSHA455MB	4.8	7.6	2.08	Mini
7	ETSHA457MB	4.8	9.6	2.08	Mini
8	ETSHA459MB	4.8	11.6	2.08	Mini
9	ETSHA404RB	4.3	6.5	2.48	Regular

10	ETSHA405RB	4.3	7.5	2.48	Regular
11	ETSHA407RB	4.3	9.5	2.48	Regular
12	ETSHA409RB	4.3	11.5	2.48	Regular
13	ETSHA454RB	4.8	6.5	2.48	Regular
14	ETSHA455RB	4.8	7.5	2.48	Regular
15	ETSHA457RB	4.8	9.5	2.48	Regular
16	ETSHA459RB	4.8	11.5	2.48	Regular
17	ETSHA504RB	5.3	6.5	2.48	Regular
18	ETSHA505RB	5.3	7.5	2.48	Regular
19	ETSHA507RB	5.3	9.5	2.48	Regular
20	ETSHA509RB	5.3	11.5	2.48	Regular
21	ETSHA604RB	6.3	6.5	2.48	Regular
22	ETSHA605RB	6.3	7.5	2.48	Regular
23	ETSHA607RB	6.3	9.5	2.48	Regular
24	ETSHA609RB	6.3	11.5	2.48	Regular
25	ETSHA704RB	7.3	6.5	2.48	Regular
26	ETSHA705RB	7.3	7.5	2.48	Regular
27	ETSHA707RB	7.3	9.5	2.48	Regular

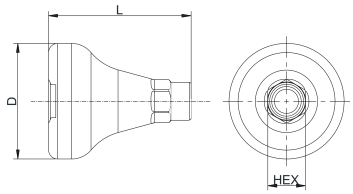
ET Scan Healing Abutment Screw



Code	A (Ø)	B (mm)	Remark
ETSHASM04	2.2	11.0	Mini

ETSHASM05	2.2	12.0	Mini
ETSHASM07	2.2	14.0	Mini
ETSHASM09	2.2	16.0	Mini
ETSHASR04	2.3	9.0	Regular
ETSHASR05	2.3	10.0	Regular
ETSHASR07	2.3	12.0	Regular
ETSHASR09	2.3	14.0	Regular

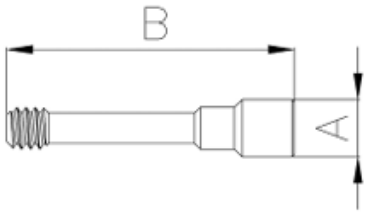
EK Scan Healing Abutment



Code	D (Ø)	L(mm)	Hex (mm)
EKSHA404B	4.3	7.8	2.08
EKSHA405B	4.3	8.8	2.08
EKSHA407B	4.3	10.8	2.08
EKSHA409B	4.3	12.8	2.08
EKSHA454B	4.8	7.8	2.08
EKSHA455B	4.8	8.8	2.08
EKSHA457B	4.8	10.8	2.08
EKSHA459B	4.8	12.8	2.08
EKSHA504B	5.3	7.8	2.08
EKSHA505B	5.3	8.8	2.08
EKSHA507B	5.3	10.8	2.08
EKSHA509B	5.3	12.8	2.08
EKSHA604B	6.3	7.8	2.08
EKSHA605B	6.3	8.8	2.08

EKSHA607B	6.3	10.8	2.08
EKSHA609B	6.3	12.8	2.08

EK Scan Healing Abutment Screw



Code	A (Ø)	B (mm)
EKSHAS04	2.1	9.5
EKSHAS05	2.1	10.5
EKSHAS07	2.1	12.5
EKSHAS09	2.1	14.5

Indications for Use:

ET Healing Abutments, ET Scan Healing Abutments and EK Scan Healing Abutments are temporary abutments used to make a natural soft tissue shape until setting up prosthesis.

Substantial Equivalence:

	Subject Device	Primary Predicate Device	Reference Device
	ET Healing Abutment	**Hiossen Implant System**	**TS Abutment System**
510(k) Number	K253372	K140934	K233194
Manufacturer	Hiossen Inc.	Hiossen Inc.	Osstem Implant Co. Ltd.
Design			
Indications for Use	Used to make a natural soft tissue shape until setting up prosthesis.	Used to make a natural soft tissue shape until setting up prosthesis	Used to make a natural soft tissue shape until setting up prosthesis
Diameter mm (D)	4.3 ~ 7.3mm	4.3 ~ 7.3mm	4.3 ~ 8.3mm
Length mm (L)	6mm, 9mm	7.5 ~ 12.5mm	3 ~ 9mm

Material	Titanium Grade 4 (ASTMF67)	Titanium Grade 4 (ASTMF67)	Titanium Grade 4 (ASTMF67)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	8 Years	8 Years	8 Years

	Subject Device	**Primary Predicate Device**	**Reference Device**
	ET Scan Healing Abutment	**ET Healing Abutment**	**TS Scan Healing Abutment**
510(k) Number	K253372	K140934	K222778
Manufacturer	Hiossen Inc.	Hiossen Inc.	Osstem Implant Co. Ltd.
Design			
Indications for Use	Used to make a natural soft tissue shape until setting up prosthesis.	Used to make a natural soft tissue shape until setting up prosthesis	Used to make a natural soft tissue shape until setting up prosthesis
Diameter mm (D)	4.3 ~ 7.3mm	4.3 ~ 7.3mm	4.3 ~ 7.3mm
Length mm (L)	6.5 ~ 11.6mm Screw: 9.0 ~16.0mm	7.5 ~ 12.5mm	5.5 ~ 11.6mm Screw: 8.0 ~16.0mm
Material	Titanium Grade 4 (ASTMF67) Screw: Titanium Alloy (ASTM F136)	Titanium Grade 4 (ASTMF67)	Titanium Grade 4 (ASTMF67) Screw: Titanium Alloy (ASTM F136)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	8 Years	8 Years	8 Years

	Subject Device	**Primary Predicate Device**	**Reference Device**
	EK Scan Healing Abutment	**EK Healing Abutment**	**TS Scan Healing Abutment**
510(k) Number	K253372	K203360	K222778
Manufacturer	Hiossen Inc.	Hiossen Inc.	Osstem Implant Co. Ltd.
Design			
Indications for Use	Used to make a natural soft tissue shape until setting up prosthesis.	Used to make a natural soft tissue shape until setting up prosthesis	Used to make a natural soft tissue shape until setting up prosthesis
Diameter mm (D)	4.3 ~ 6.3mm	4.0 ~ 8.0mm	4.3 ~ 7.3mm
Length mm (L)	7.8 ~ 12.8mm Screw: 9.5~14.5mm	3.0 ~ 7.0mm	5.5 ~ 11.6mm Screw: 8.0 ~16.0mm
Material	Titanium Grade 4 (ASTMF67)	Titanium Grade 4 (ASTMF67)	Titanium Grade 4 (ASTMF67)

	Screw: Titanium Alloy (ASTM F136)		Screw: Titanium Alloy (ASTM F136)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	8 Years	8 Years	8 Years

The information and data provided in this submission established the ET Healing Abutments, ET Scan Healing Abutments and EK Scan Healing Abutments presented in this submission are substantially equivalent to the predicate devices based on the intended use, materials, dimensions, and methods of sterilization.

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 Healing Abutments, ET Scan Healing Abutments and EK Scan Healing Abutments presented in this submission 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 subject devices. 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 ET Healing Abutments and ET Scan 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 ET healing and scan healing abutments and includes acceptance of prior LAL endotoxin testing information from prior clearance.

The EK Scan Healing Abutments are gamma irradiated under the same conditions and process as the predicate device, the EK Healing Abutment (K203360) 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 Scan Healing Abutments and includes acceptance of prior LAL endotoxin testing information from prior clearance.

Shelf Life

The ET Healing Abutment, ET Scan Healing Abutment and EK Scan Healing Abutment shelf life are identical to their respective predicate devices HIOSSEN Implant System (K140934) and EK Dental Implants and Abutments (K203360) which have 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, 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

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 ET Healing Abutments, ET Scan Healing Abutments and EK Scan Healing Abutments have the same design, intended use, structure, diameters, lengths, material surface, sterilization and packaging as the predicate devices listed in this submission and are substantially equivalent. The subject devices do not pose any new or increased risk as compared to both the legally marketed predicate and reference devices.