Hiossen, Inc.
Martin Shin
Regulatory Affairs Specialist
85 Ben Fairless Dirve
Fairless Hills, Pennsylvania 19030

January 29, 2026

Re: K251427
Trade/Device Name: EK Multi Angled 30 Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 14, 2025
Received: December 31, 2025

Dear Martin Shin:

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 Steen
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K251427

Device Name
EK MULTI ANGLED 30 ABUTMENT

Indications for Use *(Describe)*
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 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

Contact Person: Mateusz Leszczak
Telephone Number: 201-266-0657

Date Prepared: January 28, 2026

Device Name:
- Proprietary Name: EK Multi Angled 30 Degree Abutments
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: Class II
- Product Code: NHA

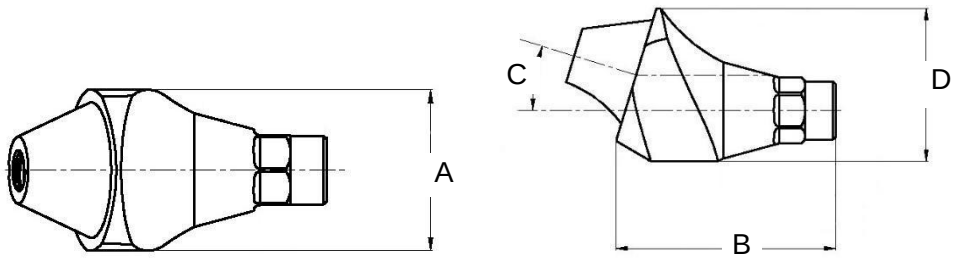
Predicate Devices:

Primary Predicate Device	**510(k)**	**Manufacturer(s)**
EK Dental Implants and Abutments System	K203360	Hiossen, Inc.
Reference Device	**510(k)**	**Manufacturer(s)**
Osstem Abutment System	K182091	Osstem Implant Co., Ltd.
TS Abutment System	K233194	Osstem Implant Co., Ltd.

Description of Device:

The EK Multi Angled 30 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 Multi Angled 30 Abutments are available in various lengths and diameters; configurations are listed in the table below.



Code	A (mm)	B (mm)	C (°)	D (mm)	Connection
EK30MA4830	4.83	7.30	30	4.82	Hex
EK30MA4840	4.83	7.80	30	4.82	Hex
EK30MA4850	4.83	8.80	30	4.82	Hex

The EK Multi Angled 30 Degree Abutments are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

Compatible Components – EK Dental Multi Angled 30 Abutment

EK Dental Multi Angled 30 Abutment are only compatible with EK Dental Implants cleared under K203360 and EK Dental D3.3 UW Implants previously cleared under K240232 (listed in the table below).

EK DENTAL IMPLANTS	Diameter (mm)	Length (mm)	FDA 510(k)
EKIII SA Implants	3.5	8.5, 10.0, 11.5, 13.0	K203360
	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 IMPLANTS	Diameter (mm)	Length (mm)	FDA 510(k)
EKIII SA D3.3 UW Implants	3.3	7.0, 8.5, 10.0, 11.5, 13.0	K240232
	6.0, 7.0	6.0, 7.0, 8.5, 10.0, 11.5, 13.0	
EKIII NH D3.3 UW Implants	3.3	7.0, 8.5, 10.0, 11.5, 13.0	
	6.0, 7.0	6.0, 7.0, 8.5, 10.0, 11.5, 13.0	

Indication for 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.

Substantial Equivalence:

The EK Multi Angled 30 Degree Abutments in this submission are substantially equivalent to the presented primary predicate and reference devices in all categories including Indications for Use, Surgical Methods, Materials, Sterilization, Surface, Dimensions, Gingival Heights and Packaging. Furthermore, the subject Multi Angled 30 Degree Abutment features the same 30-degree angulation as the previously cleared Osstem Abutment System reference device.

Device	**Proposed Subject Device** **EK Multi Angled 30 Dental Abutments**	**Primary Predicate Device** **EK Dental Abutments**	**Reference Predicate Devices** **Osstem Abutment System** **TS Abutment System**	**Similarities/** **Differences**
Manufacturer	Hiossen, Inc.	Hiossen, Inc.	Osstem Co., Ltd.	
510(K) No.	New device	K203360	K182091 K233194	
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 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.	Equivalent
Surface	Machine surface	Machine surface	Machine surface	Equivalent
Material	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)	• Titanium alloy Ti-6Al-4V (ASTM F 136)	Equivalent
Sterilization	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user	• Delivered non-sterilized • Steam sterilized by user	Equivalent
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.	• Housed in Tyvek-lidded blister tray • Placed in a tamper-evident outer package.	Equivalent

Device	Proposed Subject Device EK Multi Angled 30 Dental Abutments	Primary Predicate Device EK Dental Abutments	Reference Predicate Devices Osstem Abutment System TS Abutment System	Similarities/ Differences
Multi Angled Design				Equivalent
Restoration Type	Multi-Unit Only	Multi-Unit Only	Multi-Unit Only	Equivalent
Diameters(mm)	4.8	4.8	4.8	Equivalent
G/H(mm)	2.5 ~ 5.0	2.5 ~ 5.0	2.5 ~ 5.0	Equivalent
Angulation	30°	17°	17°, 30°	Equivalent

The only difference is that the subject Multi Angled 30 Degree Abutment features an angulation of 30 Degrees whereas the Primary Predicate EK Dental Abutment features an angulation of 17 Degrees.

The proposed subject devices add an additional angle abutment offering to Primary Predicate (EK Dental Abutment) devices previously cleared under FDA 510(k) K203360. The addition of 30 Degree angle is novel as similar devices have been previously cleared by the same manufacturer as evidenced by the Osstem reference devices under (K182091) (K233194). These additions are negligible to the point it does not change the intended use, surgical method & material and does raise questions about safety and effectiveness.

While the indications for use for both the subject device and primary predicate include crown restoration, the subject device is only for multi-unit but is being added to the system of abutments previously cleared in K203360, which included both single and multi-unit restorations. Therefore, the indications are written to match the indications for the previously cleared abutment system to which this specific multi-unit abutment is being added.

In conclusion the EK Multi Angled 30 Degree Abutments do not raise new questions of safety or effectiveness. We find that the EK Multi Angled 30 Degree Abutments are substantially equivalent to the previous cleared predicate devices.

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 Multi Angled 30 Abutments 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

Just like the predicate devices listed in this submission, the EK Multi Angled 30 Dental Abutments (manufactured using the same manufacturing process, material and utilizes the same packing materials) and are provided non-sterile. Like the predicate devices the subject devices can be moist heat sterilized using the validated process in accordance with 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 Multi Angled 30 Dental Abutments.

Shelf Life

EK Multi Angled 30 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 non-mechanical, non-active materials therefore, degradation in performance characteristics is not likely.

Surface Treatment Characterization Testing

The EK Multi Angled 30 Dental Abutment surfaces are manufactured 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 EK Multi Angled 30 Dental Abutments.

Fatigue Testing

Mechanical testing of EK Multi angled 30 Degree abutment was tested in accordance to ISO 14801 Dentistry — Implants — Dynamic fatigue test for endosseous dental. The test specimens were selected based on the worst-case configuration (smallest diameter fixture combined with the abutment yielding the longest moment arm)

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 Multi Angled 30 Dental Abutments 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.