October 10, 2025

Osseofuse International Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

Re: K243078
Trade/Device Name: HexaPLUS S OneDrill Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 13, 2025
Received: September 12, 2025

Dear Priscilla Chung:

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.

510(k) Number *(if known)*
K243078

Device Name
HexaPLUS S OneDrill Implant System

Indications for Use *(Describe)*
The HexaPLUS S OneDrill Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. The system 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.

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

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510(k) Summary
(K243078)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 10/9/2025

1. Submitter/Applicant

Osseofuse International Inc.
6170 West Desert Inn Rd. Suite B
Las Vegas, NV 89146
Tel: +1-888-446-9995
Email: support@osseofuse.com

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160, Irvine CA 92612
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: HexaPLUS S OneDrill Implant System
- Common Name: Dental Implant System
- Classification: Class II
- Classification regulation: 21 CFR 872.3640
- Product Code: DZE, NHA

4. Predicate Devices:

Primary Predicate Device:

- Conical Plus Implant System (K181157) by OsseoFuse International, Inc.

Reference Devices:

- Osseofuse Dental Implant System (K131748) by OsseoFuse International, Inc.
- Osseofuse Dental Implant System (K110577) by Dynamic Innovations Inc.

5. Description:

The HexaPLUS S OneDrill Implant System is a dental implant system made of Titanium 6AL 4V ELI Gr.23 alloy intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the indications for use, the technology used, the material compositions and performance characteristics. The surface of the implants are treated by SLA method. Implants with 4.50mm and 5.25mm body diameter are provided in lengths of 8.5, 10, 11.5, 13.0, 14.5, and 16 mm. Implants with 6.5mm and 7.5mm body diameter are provided in lengths of 8.5, 10, 11.5, 13.0, and 14.5.

The system includes the following components.

Fixtures

- Size: 4.50mm (Dia.) x 8.5/10.0/11.5/13.0/14.5/16.0mm (L)
- 5.25mm (Dia.) x 8.5/10.0/11.5/13.0/14.5/16.0mm (L)
- 6.50mm (Dia.) x 8.5/10.0/11.5/13.0/14.5
- 7.50mm (Dia.) x 8.5/10.0/11.5/13.0/14.5

Abutments

- Healing Abutment
- One-Step Abutment
- Final Cement Abutment
- Straight Abutment
- Angled Abutment
- Temporary Abutment
- Ball Abutment

Cover Screw

- Size: 3.45mm (Dia.) x 4.9

Abutment Screw

- Size: 2.30mm (Dia.) x 8.25

Multi Angle Abutment Screw

- Size: 2.30mm (Dia.) x 8.20

6. Indication for use:

The HexaPLUS S OneDrill Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and

terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. The system is intended for delayed loading.

7. Performance Data

- Fatigue testing was performed on the angled abutments according to ISO 14801.
- Sterilization, Shelf-life validation and biocompatibility are leveraged from the predicate device (K181157).
- SEM and EDS testing was conducted on the subject devices to verify that there is no residual on the implants after the surface treatment.
- Bacterial Endotoxins Test (BET) is performed using a kinetic Limulus Amebocyte Lysate (LAL) assay with a Portable Test System (PTS), in accordance with USP <85>, USP <161>, and ANSI/AAMI ST72:2019.
- A non-clinical worst-case MRI assessment was conducted for the HexaPLUS S OneDrill Implant System to evaluate its behavior in the MRI environment. The evaluation was based on scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan (2019) Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. Journal of Testing and Evaluation 49.2, 783-795) and considered the complete system, including all compatible implant bodies, dental abutments, and fixation screws, as well as their material compositions. The rationale addressed relevant parameters in accordance with the FDA guidance *"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"*, specifically evaluating magnetically induced displacement force and torque.

8. Basis for Substantial Equivalence

The HexaPLUS S OneDrill Implant System is substantially equivalent to the predicate device, Conical Plus Implant System (K81157) made by our company.

Comparison Chart

	Subject Device	Predicate Device	Reference Device
510(K) Number	K243078	K181157	K110577
Device Name	HexaPLUS S OneDrill Implant System	Conical Plus Implant System	OsseoFuse Dental Implant System
510k Applicant	OsseoFuse International, Inc.	OsseoFuse International, Inc.	Dynamic Innovations Inc.
Indications for Use	The HexaPLUS S OneDrill Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture	The Conical Plus Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, In support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture	The OsseoFuse Dental 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,

	restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. The system is intended for delayed loading.	restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. The systems is intended for delayed loading.	or overderiture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.
Principle of Operations	- Threaded Fixation - Combined with various abutments and attachments	- Threaded Fixation - Combined with various abutments and attachments	- Threaded Fixation - Combined with various abutments and attachments
Design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design
Appearance			
Implant Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	SLA Treatment on the fixture body	SLA Treatment on the fixture body	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma
Implant Diameters	4.5mm, 5.25mm, 6.5mm, 7.5mm	3.75mm, 4.5mm, 5.25mm, 6.5mm, 7.5mm	3.75mm, 4.1mm, 4.5mm, 5.25mm
Implant Lengths	8.5 – 16.0 mm	8.5 – 16.0 mm	8.5 – 16.0 mm

Abutments			
510(K) Number		K243078	K110577
Device Name		HexaPLUS S OneDrill Implant System	Hexa Plus System
510k Applicant		OsseoFuse International, Inc.	OsseoFuse International, Inc.
Healing Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.00mm, 4.70mm, 5.50mm	4.00mm, 4.70mm, 5.50mm
	Cuff	3.0mm, 5.0mm, 7.0mm	3.0mm, 5.0mm, 7.0mm
	Lengths	7.9mm, 9.9mm, 11.9mm	7.9mm, 9.9mm, 11.9mm
	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.00mm, 4.70mm, 5.50mm	4.00mm, 4.70mm, 5.50mm
	Cuff	3.0mm, 5.0mm, 7.0mm	3.0mm, 5.0mm, 7.0mm
	Lengths	8.9mm, 10.9mm, 12.9mm	7.9mm, 9.9mm, 11.9mm
	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	7.00 mm, 8.00 mm	7.10 mm, 8.10 mm
	Cuff	3.5 mm, 5.0 mm, 7.0 mm	3.0 mm, 4.0 mm, 5.0 mm, 7.0 mm
	Lengths	8.90 mm, 9.40 mm, 10.90 mm, 12.90 mm	9.40 mm, 10.40 mm, 11.40 mm,

			13.40 mm, 15.40 mm
	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.00 mm, 4.70 mm, 5.50 mm	4.00mm, 4.70mm, 5.50mm
	Cuff	3.0 mm, 5.0 mm, 7.0 mm	3.0mm, 5.0mm, 7.0mm
	Lengths	8.90 mm, 10.90 mm, 12.90 mm	7.9mm, 9.9mm, 11.9mm
	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	7.00 mm, 8.00 mm	7.10 mm, 8.10 mm
	Cuff	3.5 mm, 5.0 mm, 7.0 mm	3.0 mm, 4.0 mm, 5.0 mm, 7.0 mm
	Lengths	8.90 mm, 9.40 mm, 10.90 mm, 12.90 mm	9.40 mm, 10.40 mm, 11.40 mm, 13.40 mm, 15.40 mm
One-Step Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.5mm, 5.25mm, 6.00mm	4.5mm, 5.25mm, 6.00mm
	Lengths	11.6mm	11.6mm

Final Cement Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	5.25mm, 6.0mm	5.25mm, 6.0mm
	Cuff	2.0mm, 4.0mm	2.0mm, 4.0mm
	Lengths	13.83mm, 15.83mm	13.83mm, 15.83mm
Straight Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	3.75mm	3.75mm
	Lengths	13.83mm	13.83mm
Angled Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	5.25 mm	5.25 mm
	Cuff	2.6 mm	2.6 mm
	Lengths	6.9 mm	6. 9mm
	Angulation	17°	17°
Temporary Abutment	Appearance		

	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.75 mm	4.75 mm
	Lengths	12.45 mm, 13.0 mm	13.0 mm
Ball Abutment	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	4.0 mm	3.58 mm
	Cuff	1.0 mm, 2.0mm, 3.00 mm, 4.0mm	3.0 mm
	Lengths	9.70 mm, 10.70mm, 11.70 mm, 12.70mm	13.15 mm
Abutment Screw	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	2.30 mm	2.30 mm
	Lengths	8.20 mm	8.20 mm
Multi Angle Abutment Screw	Appearance		
	Implant Material	Ti 6Al 4V ELI Gr. 23.	Ti 6Al 4V ELI Gr. 23.
	Sterilization Method	Steam	Steam
	Diameters	2.30 mm	2.30 mm
	Lengths	8.20 mm	8.20 mm
Cover screw			
510(K) Number		-	K131748
Device Name		HexaPLUS S OneDrill Implant System	Osseofuse Dental Implant System
510k Applicant		OsseoFuse International, Inc.	OsseoFuse International, Inc.

Contract Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.
Appearance		
Implant Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Sterilization Method	Steam	Steam
Diameters	3.45 mm	3.45 mm
Lengths	4.90 mm	4.90 mm

Substantial Equivalence Discussion

The proposed subject device has the identical indications for use, technological characteristics, design and mode of operation as the above identified predicate device. The proposed device has the identical intended use as the predicate and is placed using the identical methodology as all selected predicate devices.
The fixture went through minor design change, so we conducted performance testing and the test result support that it does not raise a concern in safety and effectiveness.
The abutments have not changed except ball abutments. But the changes in design and size are minor enough not to raise a concern in safety and effectiveness.

Based on the information submitted herein, we conclude that the subject device is substantially equivalent to the predicate device.

9. Conclusion

The new device and the predicate device are substantially equivalent in the areas of technical characteristics, raw material, and design. The new device does not introduce a fundamentally new scientific technology, and the validation activities demonstrate that the subject device is substantially equivalent to the predicate device.