October 5, 2023

OsteoCentric Technologies
Todd Evans
Senior Director Quality and Regulatory Affairs
75 W 300 N Suite 150
Logan, Utah 84321

Re: K230242
Trade/Device Name: OsteoCentric Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 5, 2023
Received: September 6, 2023

Dear Todd Evans:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230242

Device Name

OsteoCentric Dental Implants

Indications for Use *(Describe)*

The OsteoCentric Dental Implants are indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The OsteoCentric Implants are indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

The OsteoCentric Dental Implants are intended to be used with the Implant Logistics 300, 400, and 500 Series abutments and healing caps.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

OsteoCentric Technologies
75 West 300 N, Suite 150
Logan, UT 84321
Phone: 1-800-969-0639

Contact Person: Todd Evans, Senior Director of Quality and Regulatory Affairs
Date Prepared: October 5th, 2023

II. Device

Device Proprietary Name:	OsteoCentric Dental Implants
Common or Usual Name:	Dental Implants
Classification Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Product Code:	DZE
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Implant Logistics Implant-One™ System, K173701, Implant Logistics, Inc.

IV. Device Description

The OsteoCentric Dental Implants consist of self-tapping and threaded endosseous implants with root-form or wide thread forms, and cover screws. The root-form implant diameters range from 3.5 mm to 5.5 mm (8 mm to 14 mm lengths) and the wide thread implant diameters are available in 4.1 mm and 4.5 mm (8 mm to 14 mm lengths), 5.5 mm (8 mm to 12 mm lengths), and 6.5 mm (8 mm to 10 mm lengths). The specific diameters and length combinations are specified below:

- Root Form Implants:
  - Ø 3.5/ 8, 10, 12, and 14 mm
  - Ø 4.0/ 8, 10, 12, and 14 mm
  - Ø 4.5/ 8, 10, 12, and 14 mm
  - Ø 5.0/ 8, 10, 12, and 14 mm
  - Ø 5.5/ 8, 10, 12, and 14 mm

- Wide Form Implants:
  - Ø 4.1/ 8, 10, 12, and 14 mm
  - Ø 4.5/ 8, 10, 12, and 14 mm
  - Ø 5.5/ 8, 10, and 12 mm

- Ø 6.5/ 8 and 10 mm

Cover screws provide protection to the threads of the connection during endosseous and gingival healing. Cover screws are pre-packaged with each implant. The OsteoCentric dental implants and cover screws are provided sterile. The implants, and cover screws are manufactured from titanium alloy (Ti-6Al-4V ELI; ASTM F136) or wrought titanium alloy (Ti-6Al-4V; ASTM F1472).

The OsteoCentric Dental Implants are intended for use with compatible abutments and healing caps manufactured by Implant Logistics. Information was shared by Implant Logistics based on a contractual license agreement which was leveraged to demonstrate implant abutment compatibility.

V. Indications for Use

The OsteoCentric Dental Implants are indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The OsteoCentric Implants are indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

The OsteoCentric Dental Implants are intended to be used with the Implant Logistics 300, 400, and 500 Series abutments and healing caps.

VI. Comparison of Technological Characteristics

The table below provides a comparison between the subject and predicate devices.

	OsteoCentric Dental Implant System	Implant Logistics Implant-One™ System (K173701)	Analysis
Endosseous Implants			
Design	Root-form Wide form	Root-form Wide-form	Identical
Material	Titanium and/or titanium alloy	Titanium and/or titanium alloy	Identical
Method of Stabilization	Threaded fixation	Threaded fixation	Identical
Implant Offerings	Root Form Implants: Ø 3.5/ 8, 10, 12, and 14 mm Ø 4.0/ 8, 10, 12, and 14 mm Ø 4.5/ 8, 10, 12, and 14 mm Ø 5.0/ 8, 10, 12, and 14 mm Ø 5.5/ 8, 10, 12, and 14 mm Wide Form Implants: Ø 4.1/ 8, 10, 12, and 14 mm Ø 4.5/ 8, 10, 12, and 14 mm Ø 5.5/ 8, 10, and 12 mm Ø 6.5/ 8 and 10 mm	Root Form Implants: Ø 3.5/ 8, 10, 12, and 14 mm Ø 4.0/ 8, 10, 12, and 14 mm Ø 4.5/ 8, 10, 12, and 14 mm Ø 5.0/ 8, 10, 12, and 14 mm Ø 5.5/ 8, 10, 12, and 14 mm Wide Form Implants: Ø 4.1/ 8, 10, 12, and 14 mm Ø 4.5/ 8, 10, 12, and 14 mm Ø 5.5/ 8, 10, and 12 mm Ø 6.5/ 8 and 10 mm	Identical

	OsteoCentric Dental Implant System	Implant Logistics Implant-One™ System (K173701)	Analysis
Implant Carrier	No Small gripping feature added	Yes	Different
Surface Treatment	Resorbable media blasted	Resorbable media blasted	Identical
Sterile	Yes	Yes	Identical
Cover Screws			
Material	Titanium and/or titanium alloy	Titanium and/or titanium alloy	Identical
Sterile	Yes	Yes	Identical

As noted in the table above, the subject and predicate devices are identical with respect to design, materials of construction, method of stabilization, implant size offerings, surface treatment, and sterility status. A gripping feature was introduced to the implant to eliminate the need for a carrier; however, as demonstrated by fatigue testing, the introduction of this feature does not impact substantial equivalence.

VII. Performance Data

The following performance data was submitted to demonstrate substantial equivalence:

- Fatigue testing per ISO 14801

Non-clinical worst-case MRI review was performed to evaluate the devices 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, dental abutments, and fixation screws) and material compositions. The 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. “

The following data was leveraged from the predicate device K173701, this information was shared based on a contractual license agreement with Implant Logistics Inc:

- Biocompatibility
- Sterilization
- Shelf-life
- Packaging Validation
- Modified Surface Testing
- Endotoxin Testing

VIII. Conclusion

The information provided above supports that the OsteoCentric Dental Implants are substantially equivalent to the predicate device.