



August 16, 2025

OsteoCentric Technologies
Todd Evans
Vice President of Quality & Regulatory Affairs
75 West 300 North
Suite 150
Logan, Utah 84321

Re: K251913

Trade/Device Name: OsteoCentric® UnifiMI® TCS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 5, 2025
Received: August 7, 2025

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.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

Assistant Director

DHT6C: Division of Restorative,
Repair, and Trauma Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251913

?

Please provide the device trade name(s).

?

OsteoCentric® UnifiMI® TCS Plating System

Please provide your Indications for Use below.

?

The OsteoCentric® UnifiMI® TCS Plating System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including but not limited to periarticular and intraarticular fractures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	OsteoCentric Technologies
Applicant Address	75 West 300 North Suite 150 Logan UT 84321 United States
Applicant Contact Telephone	435-757-2253
Applicant Contact	Mr. Todd Evans
Applicant Contact Email	todd.evans@osteocentric.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	OsteoCentric® UnifiMI® TCS Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190430	OsteoCentric Bone Plate and Screw System	HRS
K140814	EVOS MINI-FRAGMENT PLATING SYSTEM	HRS
K250494	OsteoCentric Bone Plate and Screw System	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The OsteoCentric® UnifiMI® TCS Plating System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions and replantations of bone and bone fragments. The purpose of the submission is for a line extension of the OsteoCentric Bone Plate and Screw System, which includes 2.7mm angle iron plates, additional screw sizes, and the inclusion of titanium as a material. The principal benefit of the proposed 2.7mm angle iron new plate geometry is that it allows for a stronger and more stable plate in a smaller form factor. Having a stronger and more stable plate in a smaller form factor has the potential clinical benefits of aiding the user in minimizing the incision required for the procedure and providing an option to the surgeon user that allows for the same strength and stability as a much larger plate, without having to disrupt as much soft tissue. This line extension has the same Indications for Use as the original system. This Line Extension will be known as the OsteoCentric® UnifiMI® TCS Plating System. , The system features angle plates and bone screws for fixation that are locking or non-locking, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel per ASTM F138 or Titanium per ASTM F136. Plates and screws are provided non-sterile. Instruments are provided non-sterile with instructions for sterilization.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The OsteoCentric® UnifiMI® TCS Plating System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula,

olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including but not limited to periarticular and intraarticular fractures.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications are similar to the primary predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device is similar in technological characteristics to the predicate devices. The principal benefit of the proposed 2.7mm angle iron plate geometry is that it allows for a stronger and more stable plate in a smaller form factor. Having a stronger and more stable plate in a smaller form factor has the potential clinical benefits of aiding the user in minimizing the incision required for the procedure and providing an option to the surgeon user that allows for the same strength and stability as a much larger plate, without having to disrupt as much soft tissue. The principle of operation and product code is identical between the subject and predicate devices. The indications for use, material, mechanical strength, sterility, bone plate sizes, and screw sizes are equivalent between the subject and predicate devices. See the Verification and Validation Section for more details.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Engineering analysis was performed to demonstrate that the new bone plates and screws did not present a new worst-case. The data demonstrates that the subject device is substantially equivalent to the predicates.