



October 27, 2025

OsteoCentric Technologies, Inc.
% Hannah Taggart
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K250520

Trade/Device Name: OsteoCentric Navigated Instruments System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 24, 2025
Received: September 25, 2025

Dear Hannah Taggart:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.

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

Submission Number (if known)

K250520

Device Name

OsteoCentric Navigated Instruments System

Indications for Use (Describe)

The OsteoCentric Navigated Instruments are intended to be used during the preparation and placement of OsteoCentric Pedicle Fasteners during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. The OsteoCentric Navigated Instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

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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K250520 510(K) SUMMARY

Submitter's Name:	OsteoCentric Technologies, Inc.
Submitter's Address:	75 West 300 North Suite 150 Logan, UT 84321
Submitter's Telephone:	800-969-0639
Contact Person:	Hannah Taggart, MS Empirical Technologies 719- 457-1152 htaggart@empiricaltech.com 
Date Summary was Prepared:	September 24, 2025
Trade or Proprietary Name:	OsteoCentric Navigated Instruments System
Device Classification Name:	Orthopedic Stereotaxic Instruments
Classification & Regulation #:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OsteoCentric Navigated Instruments System is a set of reusable surgical instruments for use with the Medtronic® StealthStation™ S8 Navigation System to assist surgeons in precisely locating anatomical structures in either open or percutaneous procedures for the placement of pedicle screws. The OsteoCentric Navigated Instruments are intended for use with the OsteoCentric Pedicle Fasteners. Additionally, the submission includes a hybrid technique for placement of the Integrity SI® Fusion implants.

The OsteoCentric Navigation Instrument System includes navigated probes, taps, drills, and drivers and are manufactured from medical grade stainless steels per ASTM F899, ASTM F276, and ASTM F138.

INDICATIONS FOR USE

The OsteoCentric Navigated Instruments are intended to be used during the preparation and placement of OsteoCentric Pedicle Fasteners during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. The OsteoCentric Navigated Instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Instrument Types
- Sizes and Functional Length of Instruments
- Manufacturing and Biocompatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K170679/K140454	Navigated CD Horizon® Solera® Screwdrivers and Taps	Medtronic	OLO	Primary
K173338	Navigated INFINITY™ Instruments	Medtronic	OLO	Additional
K221332	OsteoCentric Spine MIS Pedicle Fastener System	OsteoCentric Technologies, Inc.	NKB	Additional

The subject device has been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance. The biocompatibility evaluation of the instruments leveraged equivalence in materials and manufacturing to previously cleared instruments (K221332). The results of these engineering analysis and evaluations show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and geometric analysis lead to the conclusion that the OsteoCentric Navigated Instruments System is substantially equivalent to the predicate device.