April 29, 2022

Camber Spine Technologies
% Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K220038
Trade/Device Name: Camber Spine Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 28, 2022
Received: March 30, 2022

Dear Christine Scifert:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

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)*
K220038

Device Name
Camber Spine Navigation System

Indications for Use *(Describe)*
Camber Spine Navigation System instruments are intended to be used in the preparation and placement of ORTHROS Posterior Stabilization System and ORTHROS MIS Posterior Stabilization System screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 MRI based model, fluoroscopy images, or digitized landmarks of 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.

510(k) Summary
Camber Spine Navigation System
28 April 2022

Company: Camber Spine Technologies
501 Allendale Rd
King of Prussia, PA 19406

Company Contact: Noel Hetrick
Director, Quality Assurance/Regulatory Affairs
(484) 427-7060
nhetrick@cambermedtech.com

Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Camber Spine Navigation System

Common Name: Orthopedic Stereotaxic Instrument

Classification: Class II

Regulation Number: 21 CFR 882.4560 (Stereotaxic Instrument)

Panel: Orthopedic

Product Code: OLO

Device Description:
Camber Spine Navigation System contains reusable instruments, provided non-sterile, including inserters, taps, probes, awls, and awl taps. These instruments are intended to be used with the Medtronic StealthStation® Navigation System and its associated NavLock arrays, to assist surgeons in precisely locating anatomical structures for preparation and placement of ORTHROS Posterior Stabilization System and ORTHROS MIS Posterior Stabilization System screws during spinal surgery. The instrumentation is designed for use with the Medtronic StealthStation® Navigation System hardware and software. These instruments are made of medical grade stainless steel according to the ASTM F899 and many include a titanium nitride coating per SAE AMS 2444A.

Indications for Use:
Camber Spine Navigation System instruments are intended to be used in the preparation and placement of ORTHROS Posterior Stabilization System and ORTHROS MIS Posterior Stabilization System screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

Substantial Equivalence:
The subject Camber Spine Navigation System is substantially equivalent to the following predicate devices:
Primary Predicate:

- Medtronic Sofamor Danek – Medtronic Navigated Instruments (K153442)

Secondary Predicates:

- Medtronic Sofamor Danek – Medtronic Navigated Instruments (K124004)
- Camber Spine – Orthros™ Posterior Stabilization System and Orthros™ MIS Posterior Stabilization (K180980)

Similar to the predicate navigated instruments, Camber Spine Navigation System instruments are intended to be used with the Medtronic's StealthStation® System to assist the surgeon in locating anatomical structures. Additionally, the Camber Spine Navigation System instruments and their predicate devices have similar technological characteristics, including design, dimensions, materials and technology, and they function in the same manner. Performance testing demonstrates that the Camber Spine Navigation System instruments are substantially equivalent to the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
The performance evaluation included a one-to-one dimensional comparison to demonstrate substantially equivalent geometry that is critical to navigation accuracy. Testing, including anatomical and navigated simulated use and accuracy and reliability testing, has been conducted to verify that the Camber Spine Navigation System instruments are appropriate for their intended use, to ensure functionality, accuracy and compatibility with the Medtronic StealthStation® System using the NavLock Tracker, and to demonstrate substantial equivalence to the predicate instruments.

Conclusion:
Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.