Medtronic Navigation
Nicole Zimmerman
Associate Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

July 11, 2018

Re: K180816
Trade/Device Name: Ziehm RFD 3D Tracker
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 16, 2018
Received: April 17, 2018

Dear Nicole Zimmerman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180816

Device Name
Ziehm RFD 3D Tracker

Indications for Use *(Describe)*
The Ziehm RFD 3D Interface is an accessory to the StealthStation System. It is intended to be used with the Ziehm Vision RFD 3D C-arm to automatically transfer to and register three dimensional images on the StealthStation System for use in image-guided spinal surgery.

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."

K180816

510(k) Summary

I. Company: Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027
Telephone Number: (720) 890-3200

Contact: Nicole Zimmerman
Associate Regulatory Affairs Specialist
Telephone Number: (720) 890-2342
Fax: (720) 890-3500
Email: nicole.r.zimmerman@medtronic.com

K. Elizabeth Waite
Principal Regulatory Affairs Specialist
Telephone Number: (720) 890-2182
Fax: (720) 890-3500
Email: elizabeth.waite@medtronic.com

Date: 30 April 2018

II. Proprietary Trade Name: Ziehm RFD 3D Tracker

III. Common Name: Orthopedic Stereotaxic Instrument

IV. Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

V. Classification: Class II

VI. Product Code: OLO

VII. Product Description:
The Ziehm RFD 3D Tracker works by making the Ziehm RFD 3D C-arm visible to the StealthStation™ Navigation Systems. The optical reflective markers in the tracker housings interact with the camera and software to identify the position and orientation of the C-arm detector in three-dimensional space.

When optical markers are inserted into the magnetic mounting sockets on the housing, the combination is then referred to as the tracker assembly. The optical markers interact with the camera and software to identify the position and orientation of the C-arm detector in three-dimensional space.

The integration interface (tracker and C-Arm) enables automatic transfer and registration of images received from Ziehm RFD 3D system within StealthStation™ system, specifically within StealthStation™ Spine software (K170011).

To enable automatic image registration, at the beginning of each scan the StealthStation™ camera captures the position of an optical tracker attached to the C-arm in relation to the patient reference frame. Upon image acquisition, the images from Ziehm RFD 3D system and associated calibration information are automatically transferred to the StealthStation™ system as a DICOM volume over an Ethernet cable. Upon completion of the DICOM volume transfer, the StealthStation™ software automatically registers the image relative to the patient reference frame.

VIII. Indications for Use:

The Ziehm RFD 3D Interface is an accessory to the StealthStation™ System. It is intended to be used with the Ziehm Vision RFD 3D C-arm to automatically transfer to and register three dimensional images on the StealthStation™ System for use in image-guided spinal surgery.

IX. Identification of Legally Marketed Devices (Predicate Devices):

StealthStation™ System Three Dimensional C-Arm Interface (K022414)

X. Comparison of the Technological Characteristics:

See **Table 5.1** for comparison of the subject device versus predicate.

Table 5.1 Comparison Summary

Feature	**Ziehm RFD 3D Tracker (subject devices)**	**K022414-StealthStation™ System Three Dimensional C-Arm Interface (w/ Ziehm Vision FD Vario 3D Tracker)**
Product Code	OLO	HAW
Classification	Class II	Class II
Intended/ Indications for Use	The Ziehm RFD 3D Interface is an accessory to the StealthStation™ System. It is intended to be used with the Ziehm Vision RFD 3D C-arm to automatically transfer to and register three dimensional images on the StealthStation™ System for use in image-guided spinal surgery.	The StealthStation™ is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation™ system 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 the scull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

Feature	Ziehm RFD 3D Tracker (subject devices)	K022414-StealthStation™ System Three Dimensional C-Arm Interface (w/ Ziehm Vision FD Vario 3D Tracker)
Principal Mode of Operation	The integration interface enables automatic transfer and registration of images received from Ziehm RFD 3D system within StealthStation™ system, specifically within StealthStation™ Spine software.	The StealthStation System Three Dimensional C-Arm Interface is intended to interact with a commercially available 3D C-Arm. The 3D dataset will be transferred to the StealthStation™ or iON™ System via DICOM. The user may then use the 3D dataset for surgical planning and/or navigation
Navigation method (optical / EM)	Optical	optical
Cleaning and sterilization methods	Manually clean the Ziehm trackers with appropriate cleaning solutions. Do not sterilize the tracker.	Manually clean the Ziehm trackers with appropriate cleaning solutions. Do not sterilize the tracker.
Accuracy testing values	0.79 mm mean 1.73 mm upper reliability 95% confidence	1.3 mm mean 2.30 mm upper reliability 95% confidence

XI. Discussion of the Performance Testing:

Testing conducted to demonstrate the performance of the Ziehm RFD 3D Trackers is summarized as follows:

Test	Description
Ziehm RFD 3D C-arm Stealth Integration Summative Validation	Provides confidence that the product can be used safely and effectively by the intended users.
Ziehm RFD 3D Integration Kit - Functional Verification	Provides confirmation that the design and implementation of the Ziehm RFD 3D Integration Kit correctly fulfills all product functional requirements.
Ziehm RFD 3D C-arm Accuracy for StealthStation™ S8	Provides confirmation that the design and implementation of the Ziehm RFD 3D Integration Kit correctly fulfills all product accuracy requirements.

XII. Conclusions

The Ziehm RFD 3D Tracker has shown through comparison to be substantially equivalent to the identified predicate device and do not raise any new issues of safety or effectiveness.