DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 13, 2017

Orthofix Inc.
% Jacki Koch
Regulatory Affairs Specialist, II
3451 Plano Parkway
Lewisville, Texas 75056

Re: K162921
Trade/Device Name: Navigated Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 8, 2017
Received: February 9, 2017

Dear Jacki Koch:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162921

Device Name
Navigated Instrument System

Indications for Use *(Describe)*
The Navigated Instrument System is indicated for use during the preparation and placement of Orthofix screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigated Instrument System reusable instruments are specifically designed for use with the BrainLab Vector Vision system and the Medtronic StealthStation System which are 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 skull, a long bone, or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Navigated Instrument System

510(k) Owner Information

Name:	Orthofix Inc.
Address:	3451 Plano Parkway Lewisville, TX 75056
Telephone Number:	214-937-2100
Fax Number:	214-937-3322
Email:	jackikoch@orthofix.com

Registration Number:	2183449
Contact Person:	Jacki Koch, Senior Regulatory Affairs Specialist
Date Prepared:	March 10, 2017

Name of Device

Trade Name / Proprietary Name:	Navigated Instrument System
Common Name:	Instrument, Stereotaxic
Product Code:	OLO
Regulatory Classification:	Class II – 21 CFR § 882.4560
Review Panel:	Orthopedic Device Panel
Predicate Devices:	K153442 – Medtronic Navigated Instrument System – Navigated Reusable Instruments for Use with StealthStation K070106 – BrainLab Navigated Instruments for use with the VectorVision System (Individually/Manual Calibrated)
Reference Devices:	K140927 – Depuy Universal Navigation Instruments for EXPEDIUM and VIPER MIS Spine System.

Reason for 510(k) Submission:
Orthofix is submitting this Traditional 510(k) premarket notification for the introduction of the new Navigated Instrument System.

Device Description

The Navigated Instrument System is comprised of manual surgical instruments for use with the BrainLab VectorVision System and the Medtronic StealthStation Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D

images) providing confirmation of hardware placement. Use of the Navigated Instrument System is limited to Taps ranging in sizes of 4.5mm to 8.5mm and bone screws ranging from 4.5mm to 8.5mm with length ranging from 25mm to 55mm.

The Navigated Instrument System Medtronic compatible instruments are comprised of Bone Awl, Bone Taps, and Bone Probes only.

The Navigated Instrument System BrainLab compatible instruments are comprised of Bone Awl, Bone Taps, Bone Probes and a variety of Screw Drivers.

Intended Use / Indications for Use

The Navigated Instrument System is indicated for use during the preparation and placement of Orthofix screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigated Instrument System reusable instruments are specifically designed for use with the BrainLab Vector Vision system and the Medtronic StealthStation System which are 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 skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices

The technological characteristics of the subject Navigated Instrument System were compared to the predicate devices in indications for use, intended use, design, technology, materials, function and performance. It was demonstrated that the subject Navigated Instrument System technology is substantially equivalent to the predicate devices.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Engineering analysis and performance data demonstrate that the subject Navigated Instrument System is substantially equivalent to the predicate devices in compatibility, accuracy, function and performance. Engineering analysis includes dimensional measurements of both the predicate devices and subject devices.

Therefore, it can be concluded that the compatibility, accuracy, function, and performance of the subject Navigated Instrument System are substantially equivalent to the predicate device when used with the Medtronic Navigated Instrument System (K153442) and the predicate BrainLab Navigated Instruments for use with the VectorVision System (K070106).

Conclusion

Based upon the information provided in this Traditional 510(k) submission, it has been demonstrated that the subject Navigated Instrument System is substantially equivalent to the legally marketed predicate devices in regards to indications for use, intended use, design, technology, functionality and performance.