February 19, 2021

OrthoPediatrics, Corp.
Yan Li
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K203573
Trade/Device Name: RESPONSE™ Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO

Dear Yan Li:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 4, 2021. Specifically, FDA is updating this SE Letter to correct a typo in the trade name in the indications for use statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shumaya Ali, M.P.H., OHT6: Office of Orthopedic Devices by phone (1-301-796-2356) or by email (Shumaya.Ali@fda.hhs.gov).

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

February 4, 2021

OrthoPediatrics, Corp.
Yan Li
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K203573
Trade/Device Name: RESPONSE™ Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 4, 2020
Received: December 7, 2020

Dear Yan Li:

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 -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

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)*
K203573

Device Name
RESPONSE™ Navigation Instruments

Indications for Use *(Describe)*
RESPONSE™ Navigation Instruments are intended to be used during the preparation and placement of Response 4.5/5.0 and 5.5/6.0 Spine System pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. These instruments are designed for use with the Medtronic® Stealthstation® S8 System (V1.2.0), 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 vertebra, can be identified relative to a CT or MR 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.

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.

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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."

510(K) SUMMARY

Submitter's Name:	OrthoPediatrics, Corp.
Submitter's Address:	2850 Frontier Drive, Warsaw, IN 46582
Submitter's Telephone:	574-267-0864
Contact Person:	Yan Li yli@orthopediatrics.com
Date Summary was Prepared:	December 4, 2020
Trade or Proprietary Name:	RESPONSE™ Navigation Instruments
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The OrthoPediatrics RESPONSE™ Navigation Instruments are reusable surgical instruments for use with the Medtronic® StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures in open procedures for preparation and placement of pedicle screw system implants.

The RESPONSE™ Navigation Instruments include taps, probes, and drivers. The RESPONSE™ Navigation Instruments are to be used with the RESPONSE™ Spine System.

All instruments are made of stainless steel per ASTM F899. Taps range in size from Ø3mm to Ø8mm. The RESPONSE™ Navigation Instruments are not compatible with implants from other manufacturers and are designed for use only with Medtronic® StealthStation® Navigation System hardware and software.

INDICATIONS FOR USE

RESPONSE™ Navigation Instruments are intended to be used during the preparation and placement of Response 4.5/5.0 and 5.5/6.0 Spine System pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. These instruments are designed for use with the Medtronic® Stealthstation® S8 System (V1.2.0), 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of 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
- Principles of Operation
- Sizes

510k Number	Trade/Proprietary/Model Name	Manufacturer	Predicate Type
K161210/K143628 K140454/K143375	Medtronic Navigated Instruments	Medtronic Sofamore Danek USA, Inc.	Primary
K193100/K181390 K160466/K150600	RESPONSE™ Spine System	OrthoPediatrics, Corp.	Reference

PERFORMANCE DATA

A detailed dimensional analysis and comparison has been conducted for subject and predicate device to support the substantial equivalence.

Additionally, the RESPONSE™ Navigation Instruments have been tested per ASTM F2554-18, "Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems".

- Single point measurement accuracy per ASTM F2554-18
- Instrument axis rotation measurement accuracy per ASTM F2554-18
- Instrument angular position perpendicular to the system camera measurement accuracy per ASTM F2554-18
- Instrument angular position parallel to the system camera measurement accuracy per ASTM F2554-18
- Distance between points measurement accuracy per ASTM F2554-18

The results of this non-clinical testing together with the dimensional analysis and comparison show that performance of the RESPONSE™ Navigation Instruments is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the RESPONSE™ Navigation Instruments is substantially equivalent to the predicate device.