March 14, 2025

OrthoPediatrics Corp.
Yan Li
Regulatory Affairs Director
2850 Frontier Dr.
Warsaw, Indiana 46582

Re: K241816
Trade/Device Name: VerteGlide Spinal Growth Guidance System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: PGM, OLO
Dated: February 14, 2025
Received: February 14, 2025

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 (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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241816

Device Name

VerteGlide Spinal Growth Guidance System

Indications for Use *(Describe)*

The VerteGlide Spinal Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome for the following subset of patients:

- Patients who may require serial magnetic resonance imaging;
- Patients with small stature;
- Patients with low body weight, compromised tissue coverage adjacent to spinal implants, or increased risk of implant associated wound healing adverse events;
- Patients at risk for implant prominence following surgery;
- Patients with hyperkyphotic spinal deformities; OR.
- Patients at elevated risk of cardiac arrest/sudden death from anesthesia associated with additional spinal surgery.

The VerteGlide Spinal Growth Guidance System is intended to be removed after skeletal maturity.

The VerteGlide Navigation Compatible Instruments are intended to be used during the preparation and placement of the VerteGlide Spinal Growth Guidance System screws. The VerteGlide Navigation Compatible Instruments have the option to be used with or without Medtronic StealthStation® System. Use of VerteGlide Navigation Compatible Instruments with Medtronic StealthStation® System during spinal surgery can assist the surgeon in precisely locating anatomical structures in the VerteGlide Spinal Growth Guidance System procedures. The Medtronic 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 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.

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510(k) Summary

I. Submitter

Submission:	Traditional 510(k) Premarket Notification
Applicant:	OrthoPediatrics Corp.
Applicant Address:	2850 Frontier Drive, Warsaw, IN 46582
Establishment Registration Number:	3006460162
Contact:	Yan Li
Contact Phone:	(574) 267-0864
Date Prepared:	March 12, 2025

II. Device

Device Trade Name:	VerteGlide Spinal Growth Guidance System
Device Classification:	II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3070
Regulation Name:	Thoracolumbosacral Pedicle Screw System
Classification Product Code:	PGM, OLO
Device Classification Name	Growing Rod System

III. Predicate Device and Reference Device

Substantial equivalence is claimed to the following predicate device:

Primary Predicate Device:

- SHILLA™ Growth Guidance System (K140750, Medtronic Sofamor Danek USA, Inc)

This submission also includes the following reference device:

Reference Device:

- Response Spine System (K181390, OrthoPediatrics Corp.)

IV. Device Description

The VerteGlide Spinal Growth Guidance System consists of longitudinal members (rods), anchors (screws), and interconnection components (cross connector and rod clamp) in a variety

of sizes to accommodate differing anatomic requirements. The VerteGlide Spinal Growth Guidance System also include surgical instruments.

The VerteGlide Spinal Growth Guidance System offers a solution for early-onset scoliosis (EOS) patients with potential for additional spinal growth. Fusion screws are used at the apex of the curve to rigidly lock the rod in place, while sliding (non-fusion) screws are used above and below the apex to stabilize but allow for continued growth. A unique rod design is used to provide rigid fixation of the fusion screws and further promote sliding of the non-fusion screws. Fixation to the bone is provided using standard fusion and non-fusion pedicle screws. While the non-fusion pedicle screws are rigidly fixed to the bone, they also allow for sliding along the rod axis during normal growth without requiring separate rod lengthening procedures. The VerteGlide Spinal Growth Guidance System allows for deformity correction and minimizes repeat surgeries needed until skeletal maturity.

The components of the VerteGlide Spinal Growth Guidance System are manufactured from titanium alloy per ASTM F136, unalloyed titanium per ASTM F67, or cobalt chromium per ASTM F1537.

V. Indications for Use

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medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

VI. Comparison of Technological Characteristics

The VerteGlide Spinal Growth Guidance System is substantially equivalent to the predicate device SHILLA™ Growth Guidance System (K140750) in that these devices have the same intended use and principle of operation, and many other similar fundamental technological characteristics. There are some differences between the predicate and subject devices in terms of materials, sizes and design features. The successful testing data provided in this submission supported that the differences between the subject and predicate devices do not raise new questions for safety and effectiveness.

VII. Performance Data

The Biocompatibility assessment and testing for the VerteGlide Spinal Growth Guidance System were performed in conformance with ISO 10993-1.

The implants of VerteGlide Spinal Growth Guidance System were evaluated in an MR Environment for RF Heating, Displacement Force and Torque, Image Artifact per ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119, and were determined to be MR Conditional and will be labeled as such.

Mechanical performance evaluations included construct static and dynamic compression testing based on ASTM F1717; dynamic four-point bending per ASTM F2193; axial, torsional grip, static and dynamic flexion extension testing per ASTM F1798; and screw pull out strength per ASTM F543; tulip-shank dissociation testing and construct wear test. Results of the mechanical testing demonstrate substantially equivalent mechanical performance of the subject device as compared to the predicate.

VIII. Conclusion

Information and data provided within the submission support the differences between the subject and predicate devices. Therefore, it is concluded that the VerteGlide Spinal Growth Guidance System is substantially equivalent to the predicate device. To address potential safety concerns related to the possibility of adverse wear debris, a 522 Order for a Post Market Surveillance Study will be issued for this device.