October 9, 2025

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

Re: K252600
Trade/Device Name: Pediatric Plating Platform | Small-Mini
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 15, 2025
Received: August 18, 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252600

Please provide the device trade name(s).

Pediatric Plating Platform | Small-Mini

Please provide your Indications for Use below.

The Pediatric Plating Platform | Small-Mini is indicated for internal fracture fixation, osteotomies, mal-unions, and non-unions of bones and bone fragments of the appendicular skeleton appropriate for the implant size. The Pediatric Plating Platform | Small-mini is intended for children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which unfused growth plates will not be compromised by fixation, and adults. If used in the femur, tibia, humerus, patella, or pelvis the Pediatric Plating Platform | Small-Mini can only be used for non-load bearing stabilization and reduction.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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:	October 4, 2025

II. Device

Device Trade Name:	Pediatric Plating Platform | Small-Mini
Common Name:	Bone Plates and Screws
Device Classification:	II
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3030 21 CFR 888.3040
Classification Product Code:	HRS HWC
Device Classification Name	Plate, Fixation, Bone Screw, Fixation, Bone

III. Predicate Device and Reference Device

Primary predicate device:

EVOS Mini-Fragment Plating System
- Smith & Nephew, Inc. K140814

Additional predicate devices:

EVOS Small Fragment Plating System
- Smith & Nephew, Inc. K170887

EVOS Small Fragment Upper Extremity Plates
- Smith & Nephew, Inc. K190253

PediLoc Fragment System
- OrthoPediatrics Corp. K140431

IV. Device Description

The Pediatric Plating Platform | Small-Mini consists of plates and screws in a variety of sizes and shapes to accommodate different anatomic requirements. The Pediatric Plating Platform | Small-Mini also includes surgical instruments.

The Pediatric Plating Platform | Small-Mini offers a selection of implantable devices, consisting of straight and shaped plates, and screws specifically designed for the appendicular skeleton appropriate for the implant size. The plates are offered in a variety of shapes (Reconstruction Plate, Strength Plate, T-Plate, L-Plate, Y-Plate, Triangle Plate, Flare Triangle Plate, Distal Radius Plate, Peri-Implant Plate, Mesh Plate, Tubular Plate, Locking Compression Plate, and Hook Plate) and lengths to accommodate the anatomy for fixation of traumatic fractures or following planned osteotomies. The plate is fixed to the bone via the choice of polyaxially locking and non-locking screws to ensure stable fixation and healing. The Pediatric Plating Platform | Small-Mini is available in 2.0, 2.4, 2.7 and 3.5 families providing a suitable range of screw and plate sizes.

The implants of the Pediatric Plating Platform | Small-Mini are manufactured from implant grade 316LVM Stainless Steel (ASTM F138 and/or F139).

V. Indications for Use

The Pediatric Plating Platform | Small-Mini is indicated for internal fracture fixation, osteotomies, mal-unions, and non-unions of bones and bone fragments of the appendicular skeleton appropriate for the implant size. The Pediatric Plating Platform | Small-mini is intended for children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which unfused growth plates will not be compromised by fixation, and adults. If used in the femur, tibia, humerus, patella, or pelvis the Pediatric Plating Platform | Small-Mini can only be used for non-load bearing stabilization and reduction.

VI. Comparison of Technological Characteristics

The Pediatric Plating Platform | Small-Mini is substantially equivalent to the predicate devices EVOS Mini-Fragment Plating System, EVOS Small Fragment Plating System, EVOS Small Fragment Upper Extremity Plates and PediLoc Fragment System in that these devices have the same intended use and principle of operation, and many other similar fundamental technological characteristics. There are some minor differences between the predicate and subject devices in terms of patient population, anatomical locations, and the designs characteristics of plates and screws. The subject device includes a mesh plate that is not present in the predicate devices; however, similar mesh plates have been previously cleared under other 510(k) submissions for plate and screw systems, supporting the acceptability of this design feature. 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 subject implants of OrthoPediatric Corp's Pediatric Plating Platform | Small-Mini in its final finished form is identical to the predicate device OrthoPediatrics PediLoc Fragment System (cleared under K140431) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The patient-contacting subject instruments of OrthoPediatric Corp's Pediatric Plating Platform | Small-Mini in its final finished form is identical to existing OrthoPediatrics Corp's instrumentation in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

The implants of Pediatric Plating Platform | Small-Mini were evaluated for use in an MR Environment using 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 Torsional Properties, Insertion and Removal Torque, Axial Pullout Strength per ASTM F543 and Static Compression Bending per ASTM F382. Results of the mechanical testing demonstrate substantially equivalent mechanical performance of the subject device as compared to the predicate.

VIII. Conclusion

The information provided above supports that the Pediatric Plating Platform | Small-Mini is as safe and effective as the predicate devices. Information and data provided within the submission support the differences between the subject and predicate devices. Therefore, it is concluded that the Pediatric Plating Platform | Small-Mini is substantially equivalent to the predicate device.