October 4, 2024

OrthoNovis, Inc.
℅ Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242343
Trade/Device Name: BPS Wrist Fracture System
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 7, 2024
Received: August 7, 2024

Dear Hannah Taggart:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director, Biomedical Engineer
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242343

Device Name

BPS Wrist Fracture System

Indications for Use *(Describe)*

The BPS Wrist Fracture System is indicated for the fixation of simple and complex intra-articular and extra-articular fractures, and for osteotomies of the distal radius in adults.
The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3.

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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K242343 510(k) SUMMARY

Submitter's Name: Submitter's Address: Submitter's Telephone:	OrthoNovis, Inc. 1 Hargrove Grade, 2F Palm Coast, Florida 32137 833-950-0127
Contact Person:	Hannah Taggart, MS Empirical Technologies 719- 457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	October 2, 2024
Trade or Proprietary Name:	BPS Wrist Fracture System
Device Classification Name:	Plate, Fixation, Bone
Classification & Regulation #:	Class II per 21 CFR §888.3030 and 21 CFR §888.3040
Product Code:	HRS
Additional Product Code:	HWC
Classification Panel:	Orthopedic - Restorative, Repair and Trauma Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The BPS Wrist Fracture System includes bone plate and bone screw implants designed for fixation of certain fractures, fusions, or osteotomies in the distal radius. To meet various patient anatomical needs, the BPS Wrist Fracture System features several sizes of distal radius plates as well as various styles and sizes of locking, non-locking, and cortical bone screws. The plates are manufactured from Commercially Pure Titanium Grade 4 per ASTM F67. The screws are manufactured from Titanium Alloy Grade 5 (Ti-6Al-4V ELI) per ASTM F136.

INDICATIONS FOR USE

The BPS Wrist Fracture System is indicated for the fixation of simple and complex intra- articular and extra-articular fractures, and for osteotomies of the distal radius in adults.

The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3.

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. The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. Predicate clearance information and labeling documentation is shown in Appendix B. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Anatomical Site for Use
- Materials of manufacture
- Plate Sizes
- Screw Styles and Sizes

Minor differences in design do not raise questions for the safety and efficacy of the subject device since the performance testing of the subject device established the substantial equivalence despite those differences.

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K191641	AFFINITY Variable Angle Distal Radius System	Industrias Medicas Sampedro S.A.S	HRS, HWC	Primary
K233919	VariAx 2 Distal Radius System	Stryker GmbH	HWC	Additional
K083694	2.4mm VA-LCP Volar Distal Radius System	Synthes (USA)	HRS	Additional

PERFORMANCE DATA

The BPS Wrist Fracture System has been tested in the following test modes:

- Static Four-Point Bending, conducted per ASTM F382, of the worst-case subject plates met the performance criteria as outlined in the FDA Guidance '*Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway*'.

- Torsional yield strength, conducted per ASTM F543, of the worst-case subject screws met the performance criteria as outlined in the FDA Guidance '*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*'.

- Driving torque of the worst-case subject screws was conducted per ASTM F543 and met the performance criteria as outlined in the FDA Guidance '*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*'.

- Axial Pullout Strength of the worst-case subject screws was evaluated using an engineering analysis, which met the performance criteria as outlined in the FDA Guidance '*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*'.

The results of this non-clinical testing show that the strength of the BPS Wrist Fracture System 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 BPS Wrist Fracture System is substantially equivalent to the predicate device.