October 2, 2025

OrthoNovis, Inc.
℅ Tawney Schwarz
Regulatory Consultant
Simple Path LLC
712 Lyndhurst Street
Unit 321
Dunedin, Florida 34698

Re: K252758
Trade/Device Name: Cannulated Screw and Kirschner (K wire) System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY, HTN
Dated: September 29, 2025
Received: September 29, 2025

Dear Tawney Schwarz:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252758

Device Name

Cannulated Screw and Kirschner (K wire) System

Indications for Use *(Describe)*

The Intended Use of the Cannulated Screw and Kirschner (Kwire) System is for the treatment and fixation of bone fractures and osteotomies of various bones including the clavicle, acetabulum, pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula.

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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510(k) #: K252758

510(k) Summary

Prepared on: 2025-09-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OrthoNovis, Inc.
Applicant Address	1 Hargrove Grade Suite 2f Palm Coast FL 32137 United States
Applicant Contact Telephone	352-807-3306
Applicant Contact	Mr. Ken West
Applicant Contact Email	kwest@orthonovis.com
Correspondent Name	Simple Path LLC
Correspondent Address	712 Lyndhurst St Unit 321 Dunedin FL 34698 United States
Correspondent Contact Telephone	910-515-0918
Correspondent Contact	Mrs. Tawney Schwarz
Correspondent Contact Email	tawney@simplepath.solutions

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cannulated Screw and Kirschner (K wire) System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC, HTY, HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K130613	Cannulated Screw and Kirschner (K wire) System	HTN
K250055	BPS - Bone Fragment Fixation Plates, Screws, and Washers	HWC
K231504	TITANEX™ MICROBEAM Screw System, TITANEX™ ARTEMIS Screw System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

Cannulated Screws and Kwires are a self-tapping, self-drilling screw with a cortico/cancellous or cancellous thread that can be guided into position by Kwire placement. Partial or fully threaded screws are available in various different lengths and diameters to provide fixation in various size bones. The screws are made of Titanium Alloy or Stainless Steel. The Kirschner Wires (Kwires) are threaded, spaded or blunt ranging from 0.8 to 1.4mm in diameter and ranging from 100 to 200mm in length and made of 316L Stainless Steel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Intended Use of the Cannulated Screw and Kirschner (Kwire) System is for the treatment and fixation of bone fractures and osteotomies of various bones including the clavicle, acetabulum, pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are similar.

Technological Comparison

21 CFR 807.92(a)(6)

Technological characteristics are similar to the provided primary and reference predicate devices, including material, design, chemical composition and principle of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following was provided in an engineering analysis:
-Cross sectional Analysis
-Axial Pullout per Chapman et al. (Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway)

No clinical tests were submitted.

Based on the engineering analysis of device characteristics, it can be concluded that the subject device does not raise different questions of safety and effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed are assessed to be substantially equivalent to the predicate devices.