February 17, 2022

Pacific Instruments Inc.
% Jared Walkenhorst
Consultant
Novare Medical Consulting
1765 Dusty Boot Dr.
Lafayette, Colorado 80026

Re: K213982
Trade/Device Name: Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: December 18, 2021
Received: December 20, 2021

Dear Jared Walkenhorst:

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,

Brent Showalter, Ph.D.
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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

Device Name

Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires

Indications for Use *(Describe)*

Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of instruments and implants into the skeletal system.

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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P·A·C·I·F·I·C® INSTRUMENTS

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510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Pacific Instruments Inc. |
| Submitter's Address: | 438 Hobron Ln, Ste 204<br>Honolulu HI 96815<br>United States |
| Contact Person: | Jared Walkenhorst<br>Novare Medical Consulting<br>720.215.9244<br>novaremedllc@gmail.com |
| Date Summary was Prepared: | 08 FEB 2022 |
| Trade or Proprietary Name: | Pacific Instrument's Orthopaedic Fixation Pins and Wires / Kirschner/ Guide Wires |
| Common or Usual Name: | Orthopaedic Fixation Pins and Wires / Kirschner/ Guide Wires |
| Classification: | Class II per 21 CFR §888.3040 |
| Product Code: | JDW, HTY |

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires are metal K-Wires and Pins in a variety of lengths, diameters, and tips to accommodate different anatomic sizes of patients. The devices are provided non-sterile and are intended to be sterilized at the point of use. All devices are manufactured from medical grade Stainless Steel.

INDICATIONS FOR USE
Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of instruments and implants into the skeletal system.

TECHNOLOGICAL CHARACTERISTICS
Pacific Instruments Kirschner and Guide Wires are identical in intended use and similar in basic shape, material, and performance characteristics to the predicate device. There are no differences in the fundamental scientific technology shared by both the subject and predicate devices.

Table 1 Predicate Devices

| **510k Number** | **Trade or Proprietary or Model Name** | **Manufacturer** | **Predicate Type** |
|---|---|---|---|
| K100736 | Orthopaedic Fixation Pins and Wires I Kirschner/ Guide Wires | SMT Shilling Metalltechnik GmbH | Primary |

PERFORMANCE DATA
Performance tests were deemed not necessary to support substantial equivalence to the predicate device. The Pacific Instruments Orthopedic Fixation Pins and Wires / Kirschner / Guide Wires were considered for conformance to dimensional, material and mechanical property standards ASTM F138-13, ASTM F366-10 and ISO 5838-1. All items in the scope were in conformance with those standards and were therefore found to be

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substantially equivalent to the predicate devices without the need to perform mechanical testing.

CONCLUSION

Pacific Instruments Kirschner and Guide Wires have the same intended use and indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices. As such, Pacific Instruments Kirschner and Guide Wires have been determined to be as safe and effective as the predicate device and no new or different questions were raised regarding the safety and effectiveness when compared to the predicate device. Therefore, the devices have been found to be substantially equivalent.