



March 28, 2019

Intellirod Spine, Inc.
Richard Navarro
President & CEO
554F White Pond Drive
Akron, Ohio 44320

Re: DEN180012

Trade/Device Name: LOADPRO™ Intraoperative Rod Strain Sensor
Regulation Number: 21 CFR 888.3090
Regulation Name: Intraoperative orthopedic strain sensor
Regulatory Class: Class II
Product Code: QFP
Dated: July 17, 2018
Received: July 19, 2018

Dear Richard Navarro:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the LOADPRO™ Intraoperative Rod Strain Sensor, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The LOADPRO™ Intraoperative Rod Strain Sensor is an intraoperative surgical tool that allows surgeons to measure unidirectional rod microstrain on posterior rods in the sagittal plane when performing spine surgery. This device is an adjunct to surgeon tactile feedback and is not intended to replace a surgeon's clinical judgment.

The LOADPRO™ Intraoperative Rod Strain Sensor is a single use, disposable tool to be used in conjunction with X-Spine Systems Fortex Pedicle Screw System for 5.5mm diameter titanium (ASTM F136) or cobalt chrome (ASTM F1537) rod configurations.

FDA identifies this generic type of device as:

Intraoperative orthopedic strain sensor. A strain sensor device is an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision-making.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 19, 2018, FDA received your De Novo requesting classification of the LOADPRO™ Intraoperative Rod Strain Sensor. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the LOADPRO™ Intraoperative Rod Strain Sensor into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the LOADPRO™ Intraoperative Rod Strain Sensor can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

| Identified Risks | Identified Mitigation Measures |
|---|---|
| Prolonged operative time due to device error or use error | Usability Testing Non-clinical Performance Testing Software verification, validation, and hazard analysis Labeling |
| Electrical shock or device failure due to interference from other devices | Electromagnetic compatibility testing Electrical safety testing |
| Infection | Sterilization validation Reprocessing validation Shelf life testing Labeling |
| Adverse tissue reaction | Biocompatibility evaluation |

In combination with the general controls of the FD&C Act, the Intraoperative orthopedic strain sensor is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be conducted:
 - a. Mechanical testing to evaluate the effect of the device on the mechanical performance of the implant and to characterize the mechanical limits of the components used with the implant; and
 - b. Accuracy and repeatability testing of strain measurements.
2. Usability testing must evaluate the effect of the device on the performance of the surgical procedure.
3. The patient-contacting components of the device must be demonstrated to be biocompatible.

4. Performance testing must support the sterility and shelf life of the patient-contacting components of the device.
5. Software verification, validation, and hazard analysis must be performed.
6. Performance data must validate the reprocessing instructions for reusable components of the device.
7. Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.
8. Labeling must include the following:
 - a. A shelf life;
 - b. Instructions for use;
 - c. Reprocessing instructions for any reusable components; and
 - d. A statement that the device is not intended to provide diagnostic information or influence clinical decision-making.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Intraoperative orthopedic strain sensor they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the LOADPRO Intraoperative Rod Strain Sensor, and substantially equivalent devices of this generic type, into Class II under the generic name Intraoperative orthopedic strain sensor.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Colin O'Neill at 301-796-6428.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health