

**DE NOVO CLASSIFICATION REQUEST FOR
LOADPRO™ INTRAOPERATIVE ROD STRAIN SENSOR**

REGULATORY INFORMATION

FDA identifies this type of device as:

Intraoperative orthopedic strain sensor. A strain sensor device is an adjunct tool 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.

NEW REGULATION NUMBER: 21 CFR 888.3090

CLASSIFICATION: Class II

PRODUCT CODE: QFP

BACKGROUND

DEVICE NAME: LOADPRO™ Intraoperative Rod Strain Sensor

SUBMISSION NUMBER: DEN180012

DATE OF DE NOVO: July 19, 2018

CONTACT: Intellirod Spine, Inc.
554F White Pond Drive
Akron, OH 44320

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.

LIMITATIONS

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The LOADPRO™ Intraoperative Rod Strain Sensor includes a titanium/zirconia ceramic, single use strain sensing device, which includes radio-frequency identification (RFID) technology (13.56MHz), intended to enable access to strain measurement values, incorporating a passive transponder, inserter, and scanner (Figure 1 and 2). The transponder attaches to X-Spine Systems Fortex Pedicle Screw System using 5.5mm titanium alloy or cobalt chrome rods in corrective spinal surgeries (Figure 3). The transponder is used only to acquire rod microstrain values and a unique device identification code, which is read by the scanner, during the surgical correction.

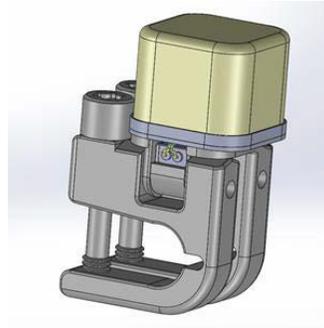


Figure 1: Profile view of the LOADPRO™ Intraoperative Rod Strain Sensor

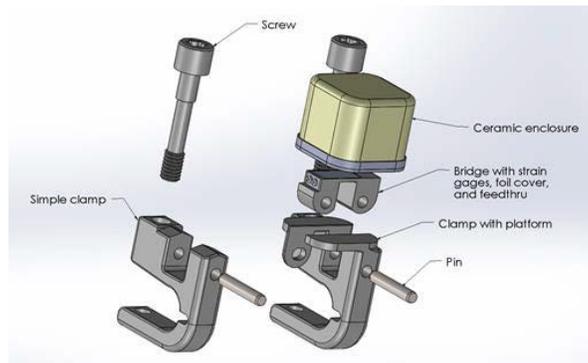


Figure 2: Profile exploded view of the LOADPRO™ Intraoperative Rod Strain Sensor

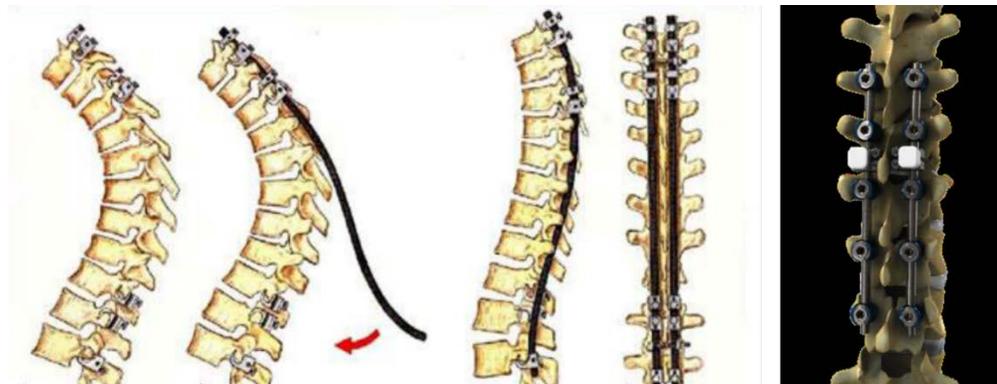


Figure 3: Image of the LOADPRO™ Intraoperative Rod Strain Sensor attached to a pedicle screw system using 5.5mm titanium alloy rods

The LOADPRO™ Intraoperative Rod Strain Sensor is a titanium/zirconia ceramic, ethylene oxide (EtO) sterilized, single use device designed to provide objective readings of the change of mechanical unidirectional strain on a pedicle screw rod. The LOADPRO™ Intraoperative Rod Strain Sensor consists of the following primary components, described in detail in the proceeding sections:

- LOADPRO™ Intraoperative Rod Strain Sensor
- Hand Held Reader (scanner)
- Manual Orthopaedic Surgical Instrumentation

LOADPRO™ Intraoperative Rod Strain Sensor

The LOADPRO™ Intraoperative Rod Strain Sensor consists of a titanium clamp and housing unit: a sealed zirconia ceramic and titanium enclosure containing a battery-less, wireless sensor, designed to provide objective readings of the change of mechanical strain in one plane on the pedicle screw and rod system during a surgical procedure. The sensing element is capable of measuring static and dynamic strain and converting it to an electrical signal. The electronic data acquisition circuitry is connected via a built-in antenna. The reading results are communicated telemetrically to a hand-held Reader unit. The LOADPRO™ Intraoperative Rod Strain Sensor, provided in a single size, is comprised of multiple sub-components (Figure 4).

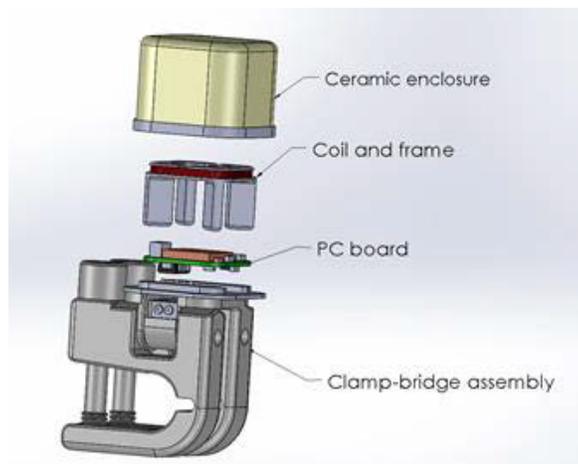


Figure 4: Profile exploded view of the LOADPRO™ Intraoperative Rod Strain Sensor electronic acquisition circuitry

The LOADPRO™ Intraoperative Rod Strain Sensors are attached directly to 5.5mm rods in the space between upper and lower pedicle screw sets. Attachment is accomplished by a straightforward non-abrasive clamp mechanism in which the clamp body surrounds the rod and a screw compresses the open side of the clamp. The LOADPRO™ Intraoperative Rod Strain Sensor monitors the rod microstrain in one plane, providing objective readings of the mechanical strain during rod manipulation to provide the surgeon with a real-time measurement of strain on the rod. The clinical significance of knowing and/or modifying unidirectional, sagittal plane rod microstrain values is unknown.

Titanium Fixation Clamps

The LOADPRO™ Intraoperative Rod Strain Sensor attaches directly to 5.5mm rods in the vertical space between the heads of adjacent level pedicle screws, on one side of the construct. Attachment is accomplished by a straightforward non-abrasive clamp mechanism in which the clamp body surrounds the rod and a screw compresses the open side of the clamp.

The LOADPRO™ Intraoperative Rod Strain Sensor allows for independent movement of the two clamps to allow clamping on straight as well as curved rods. The clamps transmit rod microstrain from the sagittal plane to the sensing element. Bench testing confirms that this attachment mechanism does not impact the mechanical integrity of the rod or rod/screw construct fatigue life.

Electronic Elements

The electronics in the LOADPRO™ Intraoperative Rod Strain Sensor consist of:

- A Strain Sensor
- Sensor Telemetry Circuit Board
- Reader Inductive Link and Display

The electronic components incorporated into the Inductive Link and Data Convertor Electronics subassembly include: antenna, resistors, capacitors, transistor (MOSFET), and integrated circuits (microchips). This is sealed in zirconia ceramic and titanium to protect the electronics.

Strain Sensor

The LOADPRO™ Intraoperative Rod Strain Sensor consists of a series of semiconductor strain gages that measure strain in a loaded element, in this case the 5.5mm rods used during rod manipulation in spine surgery. The semiconductor strain gage is commercially available and has history of use in aeronautical, military, and medical device applications.

Sensor Telemetry Circuit

A radio frequency telemetry circuit is used to transmit data to a hand-held Reader. The telemetry circuit and sensor are powered by inductive coupling from the Reader, thus no power source is needed in the Sensor.

The strain measurement electronics are powered wirelessly using inductive coupling. Power is provided by a 13.56 MHz electro-magnetic field sourced by a reader coil that is placed near the sensor. This same inductive link is used to transfer data from the Sensor to the Reader. If the Reader antenna is not close enough to the Sensor's antenna to fully operate the device, any partial / corrupt data will be rejected by the Reader. This technology is derived from RFID short-range systems used worldwide and is robust and dependable. The Sensor's circuit rectifies the power signal for operation of a field-programmable gate array (FPGA) integrated circuit and strain sensor. An oscillator (resistance to frequency converter) is used to measure the resistance of the strain sensor. The signal is then conditioned and used to modulate a load placed across the

Sensor's coil. The Reader detects the Sensor's signal as a varying load. The nominal data frequency is 33 kHz (a 66-bit data packet transmitted in 2 msec bursts).

Hand Held Reader

The LOADPRO™ Reader is a handheld electronic device that is used to read the LOADPRO™ Intraoperative Rod Strain Sensor. It consists of an integrated antenna, display screen, and “Scan” and “Clear” buttons. When a reading is required, the Reader is powered on and the Scan button pressed. The Reader (inside a sterile sheath) is then placed near the patient in proximity of the Sensor to begin data collection. The Reader receives the data from the Sensor, performs validity checks and then displays the value for that reading in units of microstrain (microinches/inch). If two Sensors are within the inductive link field, data from both Sensors are displayed (one on each line with their corresponding serial numbers).

Handheld LOADPRO™ Reader

The LOADPRO™ Reader utilizes a Microchip PIC microcontroller (Figure 5). The primary functions of the reader include:

- Transmit signal to power the sensor
- Read data from the sensor
- Determine if data reading is valid
- Display valid readings

The reader software is designed to be streamlined and simple. The user interface requires the user to power the reader on (slide switch), press a button (Scan) to initiate reads, press a different button (Clear) to clear the screen and turn off the inductive link.

When a data is obtained from the Sensor(s), the Reader software confirms it is an acceptable reading through a series of validity checks such as checksum verification and data range parameters. If the reading does not pass all validity checks, the data is discarded and the next reading is collected.

The Sensor continuously collects and sends data to the Reader as long as the inductive link provides power.

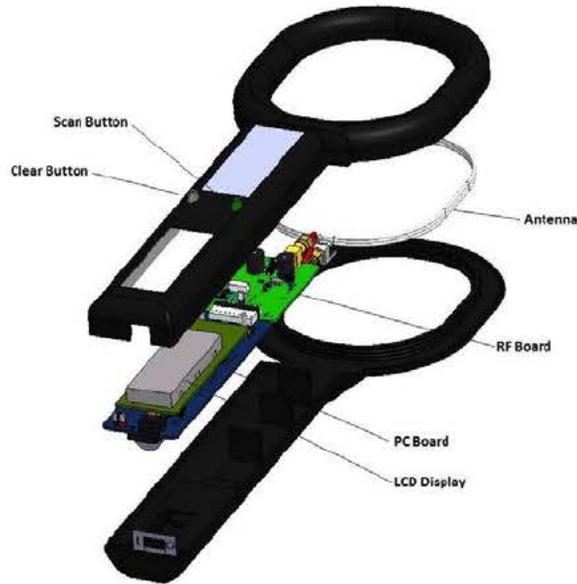


Figure 5: Exploded view of the LOADPRO™ Reader

Manual Orthopedic Surgical Instrumentation

Manual orthopedic surgical instruments are used for the connection of the LOADPRO™ Intraoperative Rod Strain Sensor.

SUMMARY OF NON-CLINICAL TESTING

BIOCOMPATIBILITY / MATERIALS

The LOADPRO™ Intraoperative Rod Strain Sensor is made from the following medical-grade materials, some of which are sealed and not patient-contacting:

- Titanium alloy (Ti6AlV-ELI) per ASTM F136/ISO 5832-3
- Nusil Med-2000 (b) (4) Silicone per ASTM D792, ASTM D2240, ASTM D412 and ASTM D624
- Titanium Niobium per AMS 4982-B
- Zirconia ceramic per ASTM D2442
- (b) (4)
- (b) (4)

The LOADPRO™ Instruments are made from (b) (4) stainless steel per (b) (4)

These components are patient contacting with limited exposure (≤ 24 hours). Biocompatibility evaluation has been completed according to FDA Guidance, “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’” <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf>. Cytotoxicity testing of the sensor has been performed

per ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity. The test articles showed no evidence of causing cell lysis or toxicity.

All other components of the system are not patient-contacting.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Electromagnetic compatibility and electrical safety testing has been performed per EN 60601-1, Medical electrical equipment Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2:2007 Third Edition, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – Requirements and tests. The test results support electromagnetic compatibility and electrical safety.

SOFTWARE / CYBERSECURITY

The LOADPRO™ software documentation and verification testing is based on a Level of Concern of Minor per FDA’s guidance document, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Failure or latent design flaws of the LOADPRO™ System are unlikely to cause any injury to the patient or operator. The device and labeling passed all relevant portions of the testing.

Software Description

The LOADPRO™ software resides on the Reader. The Reader is the interface between the Sensor and the Physician. The physician registers a Sensor to the Reader through the Reader’s user interface. After Sensor registration, the Reader collects data from the Sensor via an inductive link and displays it on the handle of the Reader.

The software requirements describe the complete functionality of the Reader software, and are summarized below:

- Software shall enable a watchdog timer on startup.
- Software shall display start-up information, including software revision.
- Software shall enter “scan mode” when the Scan Button is pressed.
- Software shall scan for available Sensors (up to 2) during “scan mode”
- Software shall display the serial number from each detected Sensor.
- Software shall calculate and display the offset data for a given Sensor based on the first Sensor reading subtracted from the current Sensor reading.
- Software shall stop displaying Sensor readings when the Clear Button is pressed, or when 10 seconds have passed without detecting a Sensor.

Verification Testing

Software verification testing was performed for the LOADPRO™ System to verify that the system functions as designed. The following methods were applied to verification testing of the system:

1. Identify each functional item in the LOADPRO™ System functional specifications
2. Create a test procedure, setup, and success criteria that focuses on each specific specification
3. Perform each procedure and record the results
4. If any procedure fails to meet the success criteria, create an entry in the LOADPRO™ Issue Tracking Database on SharePoint
5. The Change Review Board reviews each failure
6. An Engineer is assigned to resolve each issue
7. Once the Issue has been resolved, tests are identified for repeat
8. Once re-tested and passed, the Issue is marked resolved and closed.
9. A Test Report shall be generated for each iteration of testing performed.
10. Testing is considered complete once all procedures have successfully passed, which indicates that all functions of the LOADPRO™ System are properly implemented.

Following completion of the verification procedure, all features pertaining to collecting and displaying sensor readings have passed the testing acceptance criteria.

Revision Level History

The current revision of the reader software is v0.0.17.D and has been verified.

Cybersecurity

Adequate risk analyses and information per FDA Guidance, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” was provided. Due to the limited connectivity and low risk of the device, the LOADPRO™ System represents a low cybersecurity risk.

PACKAGING, STERILIZATION, CLEANING, AND SHELF LIFE

LOADPRO™ Intraoperative Rod Strain Sensor

The LOADPRO™ Intraoperative Rod Strain Sensors are single use devices provided clean and sterile to the end user.

Sterilization methods of the device has been validated in accordance with ISO 11135, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for

development, validation and routine control of a sterilization process for medical devices, to ensure a sterility assurance level (SAL) of 10⁻⁶ before the device is marketed.

Accelerated aging to support a six (6) month and a twelve (12) month shelf life was performed for the EO-sterilized LOADPRO™ Intraoperative Rod Strain Sensors per ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Medical Device Packages. The expiration date of 12 months was verified by demonstrating package integrity through dye penetration and burst testing on the stored pouches.

LOADPRO™ Instruments

All LOADPRO™ Instruments are provided non-sterile and should be cleaned and sterilized prior to use. Steam sterilization methods per AAMI ST79 and ISO17665-1, Half Cycle Method (Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices) were validated to ensure a sterility assurance level (SAL) of 10⁻⁶.

Cleaning methods have been validated to ensure a sterility assurance level (SAL) of 10⁻⁶ in accordance with AAMI ST79.

PERFORMANCE TESTING-BENCH

Rod Durability

Bench testing was performed to assess the effects that repetitive installations of a sensor might have on the mechanical performance and the fatigue endurance of pedicle screw system components and constructs.

LOADPRO™ Intraoperative Rod Strain Sensors are sized for use on Ø5.5mm titanium alloy rods. The Fortex™ Pedicle Screw System (K090224) was obtained from X-Spine for the static and dynamic evaluation of the systems' rod (and construct) integrity as a representative for all predicate screw systems with Ø5.5mm rods.

Dynamic ASTM F1717-13 compression bend runout testing was performed identical to the testing provided in the Fortex 510(k). Testing was performed on non-sensored rods and on sensed rods after fifteen (15) LOADPRO™ Intraoperative Rod Strain Sensor installations / removals were performed at the same location. The results (Table 1) indicate there was no change between the sensor and non-sensor groups.

Table 1: Dynamic Compression Bend Testing Results – Runout to 5M Cycles

Non-Sensored Rod	Sensored Rod (15 times)
(b)	(b)

The static cantilever bend tests for the non-sensored and repetitive sensor implantation rods were run for 3 samples per group per ASTM F2193-2. A larger sample size was not needed for each group as the dynamic ASTM F1717 in compression bend to five million cycles is more predictive of potential titanium damage than a static test would be.

Table 2: Static Bend Testing Results

Rod	Mean Bend Strength (N/m)	Mean Bending Stiffness (N/m)
Non-Sensored Rod	216.5 ± 18.9	72.70 ± 0.72
Sensored Rod	201.57 ± 4.7	77.47 ± 6.53

There was no meaningful difference in strength and stiffness per the static cantilever bend tests, and the dynamic compression bend run-out loads were equivalent between groups.

System Characterization Testing

Tests were performed to characterize the sensor/reader as part of the LOADPRO™ System. A summary of the testing results is provided below.

Test 1: Kyphotic Rod Function Testing

Test 1, Kyphotic Rod Functional Testing and Test 3, Sensor Characterization Testing focus on the sensor verification testing. Please see ACCURACY AND REPEATABILITY TESTING Section below.

Test 2: Sensor Limit Testing

Test 2 was performed to show that the disposable sensor can withstand high levels of strain on the rod to which they are attached. This ratio should be close to 4:1 (4 μ strain on the rod = 1 μ strain on the bridge). Using this ratio, the rod strain when the bridge sees 2000 μ strain is calculated. The acceptance criterion requires the rod strain value be greater than the yield strain for each material (Ti > (b) (4) strain, CoCr > (b) (4) strain).

Test 3: Sensor Variability Testing

Test 3 focuses on Sensor-to-Sensor variations and ensures that all incoming sensors can repeatably measure strain and function similarly. In this setup, an ASTM F1717 construct was used. The LOADPRO™ Intraoperative Rod Strain Sensors were mounted on one rod and a strain gage on the other rod. Using the test machine, the F1717 construct was loaded to specific loads of 50N, 100N, 150N, 200N, -50N, -100N, -150N, and -200N. The max load was limited to +/- 200N as this equates to (b) (4) strain, which is the elastic deformation limit for Cobalt/Chrome rods. Strain values were recorded as determined by the LOADPRO™ Intraoperative Rod Strain Sensors for comparison at

each load. These test results (Figure 6 and Table 3) show that the LOADPRO™ Intraoperative Rod Strain Sensors measure strain linearly and are not load dependent.

Table 3: Sensor to Sensor Resistance Variability

Load (N)	Variability in resistance
-50	9.9%
-100	6.2%
-150	5.8%
-200	5.2%

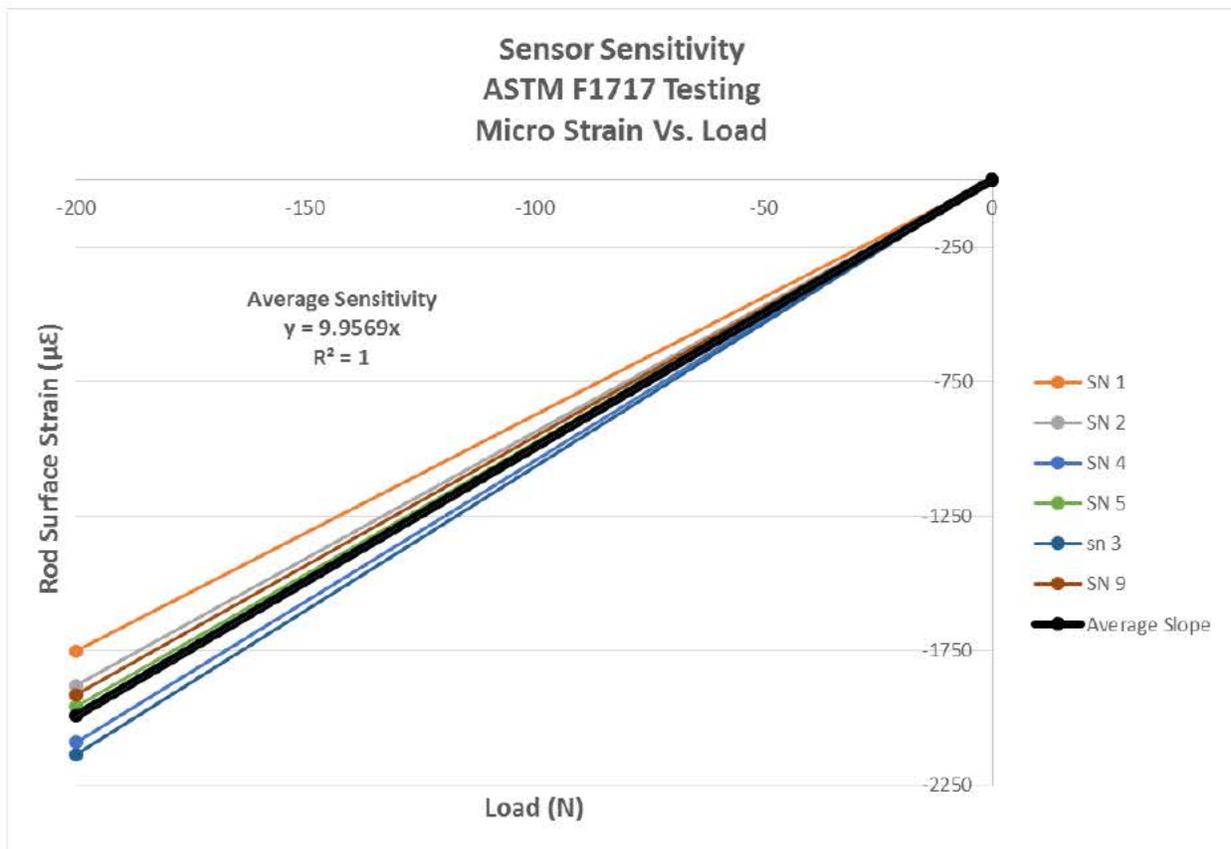


Figure 6: Sensor to Sensor Variability Results

Test 4: Sensor Longevity Test

The sensor longevity testing was performed to assess the accuracy of the sensor when seated on the rod construct for 8 hours with strain readings recorded every hour. Eight hours was selected as a period of time that would exceed a normal surgery.

Test 5: Sensor Temperature Variability Test

The sensor temperature variability testing was performed to assure that the sensors will not dramatically change in strain value as the environmental temperature fluctuates within the limits of an operating room environment (65°F, 70°F, 75°F).

Test 6: Reader Duration Test

The reader duration test evaluated the Reader in scanning mode for 5 minute intervals up to 120 minutes of total scanning time to ensure that the Reader can function without the need to change the batteries for the entire duration of a typical surgery.

Accuracy and Repeatability Testing

Test 1 described above verified that the system can accurately and repeatably measure the load placed on a cantilevered rod. Two (2) cantilevered rods, one with a strain gage mounted to the rod and the other with the LOADPRO™ Intraoperative Rod Strain Sensor were used. The same load was applied to both rods so that the mounted strain gage recorded 1400 µ-strain. Strain data was then collected from the LOADPRO™ Intraoperative Rod Strain Sensor (Ti Rods: Figure 7 and Table 4; CoCr Rods: Figure 8 and Table 5). This test was performed with both Titanium Alloy (Ti) and Cobalt/Chrome (CoCr) rods, and all tested Sensors passed the success criteria.

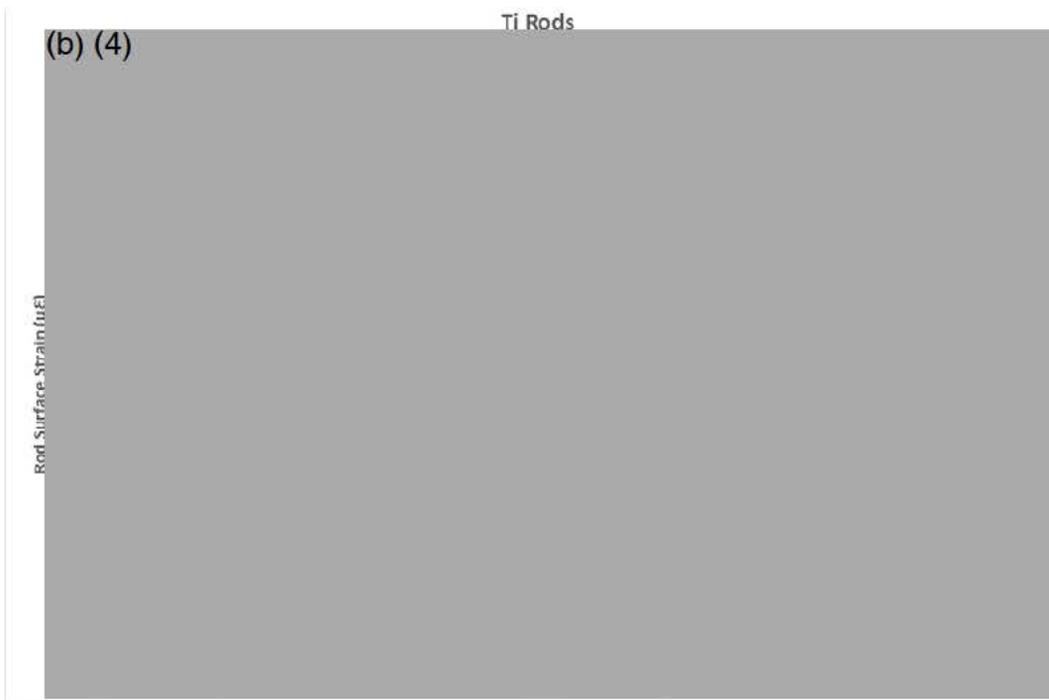


Figure 7: Cantilever Bend Measurement Accuracy Results – Titanium Rods

Table 4: Measurement Accuracy Results – Titanium Rods

Ti Rods, Strain (b) (4)			
SN	Delta Resistance (KΩ)	Sensor Strain (με)	%Error
(b) (4)			

CoCr Rods			
(b) (4)			

Figure 8: Cantilever Bend Measurement Accuracy Results – Cobalt Chrome Rods

Table 5: Measurement Accuracy Results – Cobalt Chrome Rods

CoCr Rods, Strain (b) (4)			
SN	Delta Resistance (KΩ)	Sensor Strain (με)	% Error
(b) (4)			

Additional performance testing was conducted to demonstrate that the LOADPRO™ Intraoperative Rod Strain Sensor provides repeatable and accurate readings despite potential sources of error. This included cantilever bend testing with rods having coronal curvature, cantilever bend testing with off axis loading, cantilever bend testing with wetted rods, and cantilever bend testing with varying ambient temperature. Tests demonstrated that individual and combined effects resulted in microstrain reading errors of less than 10%.

USABILITY TESTING

Table Top Usability Study

Usability testing was performed using a table top spine model to obtain feedback from end-user spine surgeons regarding the usability of the LOADPRO™ System (instruments, sensor, and reader).

A modified usability scale^{1,2}, was used to measure usability effectiveness and usability issues requiring attention with added terminology related to the LOADPRO™ product. Currently practicing orthopedic spine surgeons and fellows were selected as the targeted user population. Each user reviewed:

1. Technique and instrument review
2. Sensor installation and removal review
3. Reader review

Each item was graded on a scale of 1 to 5 (strongly disagree to strongly agree) and converted to an overall score ranging from 0 to 100. An adjusted total score of 70 or greater was determined to be acceptable based on the scoring and grading system in Brooke and Duncan. A score less than 70 would require a review by the sponsor and adjustment based on the user’s feedback. The results of the usability testing are summarized in Table 6. The average score for each application was above the acceptance criteria of 70.

Table 6: Usability Results (15 Users)

Application	Average Score
Instruments	89.5 ± 12.8
Sensor	84.5 ± 12.3
Reader	85.7 ± 13.2

Additional user feedback from the participating surgeons was incorporated into the design and instructions for use of the device. The usability testing did not reveal any end-user problems with device usage.

¹ Brooke JB and Duncan KD. Effects of system display format on performance in a fault location task. *Ergonomics* (1981); 24:175-189.

² Brooke J. A “quick and dirty” usability scale. In P.W. Jordan, B. Thomas, B.A. Weerdmeester, and AL McClelland (Eds), *Usability Evaluation in Industry*. London: Taylor and Francis (1996).

Intraoperative Usability Testing

The sponsor conducted an intraoperative usability test on five patients undergoing posterior spinal surgeries. The four participating surgeons were blinded to the values obtained by the sensors. A total of 13 sensors were used in six surgeries* at two clinical sites. Summary data for the surgical cases is shown in Table 7 below.

Table 7: Summary of Intraoperative Usability Testing – Estimated Blood Loss and Operating Time

Patient #	Clinical Site	M/F	Age	# of sensors used	Total Blood Loss (cc)	Est. Blood Loss during LOADPRO use (cc)	Total O.R. Time (hrs: mins)	LOADPRO O.R. usage time (min: sec)
1	(b) (6)			2	1,100	0	4hrs 41min	16min 30sec
2				1	3,000	<5	8hrs 43min	7min 12sec
2*				2	400	<5	3hrs 04min	11min 12sec
3				3	300	<5	6hrs 47min	8min 30sec
4				3	1,100	5 to 50	6hrs 53min	11min 55sec
5				2	1,200	5 to 50	5hrs 04min	13min 19sec

*Patient had surgery over two separate days

During these cases the LOADPRO™ Intraoperative Rod Strain Sensor has demonstrated the ability to obtain measurements in an intraoperative setting. Based upon surgeon feedback related to estimates of attributed blood loss and time of sensor usage, the LOADPRO™ Intraoperative Rod Strain sensor does not appear to significantly prolong operative times.

LABELING

The LOADPRO™ Intraoperative Strain Sensor labeling consists of the following: device description, indications for use, instructions for use, contraindications, warnings, and precautions, shelf life, and disposal instructions. The labeling meets the requirements of 21 CFR 801.109 for prescription devices and specifically indicates that the device should not be used to make a diagnosis or replace the surgeon's clinical judgement. Furthermore, the sterile packaging includes a shelf life for the device, and the labeling includes reprocessing instructions for the reusable instruments.

RISKS TO HEALTH AND IDENTIFIED MITIGATION MEASURES

Table 8 identifies the risks to health that may be associated with use of an intraoperative orthopedic strain sensor and the measures necessary to mitigate these risks.

Table 8 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Prolonged operative time due to device failure 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

SPECIAL CONTROLS

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.

BENEFIT/RISK DETERMINATION

The sponsor has collected adequate data to assess the safety profile of the subject device and identified that there are benefits (e.g., obtaining an accurate measurement of sagittal rod strain). The risks of the device are based on the usability study described above. Types of harmful risks include increased operative time and consequent increased blood loss. An average increased operative time attributed to the use of the subject sensor device is not overly prolonged in the context of total operative time. The surgeon estimated blood loss attributed to the use of the device is negligible.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for use as an intraoperative tool that measures relative unidirectional strain on a posterior pedicle screw rod, the probable benefits outweigh the probable risks for the LOADPRO™ Intraoperative Rod Strain Sensor. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the LOADPRO™ Intraoperative Rod Strain Sensor is granted and the device is classified under the following:

Product Code: QFP
Device Type: Intraoperative orthopedic strain sensor
Class: II
Regulation: 21 CFR 888.3090