

**DE NOVO CLASSIFICATION REQUEST FOR
RUTHLESS SPINE RJB**

REGULATORY INFORMATION

FDA identifies this type of device as:

Intraoperative surgical angle measurement tool. An intraoperative surgical angle measurement tool attaches to surgical instruments to measure the angle of the instrument relative to a vertical plumb line in line with gravity. The tool does not utilize anatomic landmarks or registration to patient anatomy.

NEW REGULATION NUMBER: 21 CFR 888.4560

CLASSIFICATION: Class II

PRODUCT CODE: QWL

BACKGROUND

DEVICE NAME: Ruthless Spine RJB

SUBMISSION NUMBER: DEN230012

DATE OF DE NOVO: February 16, 2023

CONTACT: Ruthless, LLC dba Ruthless Spine
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INDICATIONS FOR USE

The Ruthless Spine RJB device is intended to measure the angle of surgical instruments in two planes relative to a vertical plumb line in line with gravity. It is indicated for use during lumbosacral pedicle screw implantation in conjunction with applicable spinal instrumentation and as an adjunct to fluoroscopy or intraoperative x-ray. The RJB device is not intended to replace a surgeon's judgment and has not undergone clinical evaluation. No clinical benefit has been demonstrated or is claimed.

LIMITATIONS

No clinical studies, Real World Data (RWD), Real World Evidence (RWE), or other information are available to evaluate the effect of patient demographics, such as race and ethnicity, on RJB device performance.

The sale, distribution, and use of the RJB device is restricted to prescription use in accordance with 21 CFR 801.109.

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

DEVICE DESCRIPTION

The Ruthless Spine RJB device (“RJB device”) is an intraoperative surgical angle measurement guide that attaches to surgical instruments to measure the angle of the instrument relative to a vertical plumb line in line with gravity. The device can measure the axial and sagittal angles relative to gravity. The RJB system only provides measurements for angles in two planes relative to the vertical gravitational plumb line. As such, the RJB device does not provide surgical assistance, guidance, or navigation against patient anatomy. The RJB device is not intended to replace a surgeon’s clinical judgement and has not undergone clinical evaluation. No clinical benefit has been demonstrated or is claimed.

The RJB device is provided sterile for single use and utilizes Bluetooth Low Energy (BLE) to connect to a tablet computer and display the angle measurements via the RJB Application (App). A set of handles and instruments compatible with the RJB are provided with the device for use in lumbosacral pedicle screw placement. The following components are part of the RJB system:

- RJB Device
- Quick Connect Axial Ratcheting Handle (2)
- Straight Probe (1)
- Duckbill Probe (1)
- RJB App

Note, a Tablet Computer is required to operate the device. The Tablet used for running the RJB App is supplied by the user and must be dedicated to RJB App use and not be used for any other purpose. The following are the minimum tablet specifications required for the RJB App:

Apple

iPad Pro 11” (4th Generation) and above

Storage: 128GB

iOS: 14 and above

Camera: Camera access is desirable but not required (device barcode may be input manually)

Bluetooth: 4.0 and above

Wi-Fi: Is required to download the app but is not necessary for App usage

Cellular connectivity: Not required

Android

Storage: 32GB

Android OS: 10 and above

Processor Specifications: 2.0 GHz

Memory: 2GB RAM

Camera: Camera access is desirable but not required (device barcode may be input manually). If camera function is utilized, minimum camera resolution is an 8MP main camera with auto-focus.

Bluetooth: 4.0 and above

Wi-Fi: Is required to download the app but is not necessary for App usage

Cellular connectivity: Not required

RJB Device

The RJB device is comprised of a printed circuit board (PCB) containing an accelerometer, BLE module, and an integrated chip with programmed firmware, powered by an on-board coin-cell battery. The entire RJB PCB is surrounded by polyolefin heat-shrink tubing. A polyimide pull-tab (orange strip in Figure 1) is inserted underneath the battery such that when it is removed from the end of the device, the RJB device is turned on and is able to be paired with a tablet for use. The device has a minimum 8-hour battery life once activated. The RJB device is identified with a serial number and scannable barcode that are used to pair the device in the RJB App.



Figure 1: RJB device (left and middle) and RJB device inserted into example device handle (right).

Once activated and paired with the App, the RJB device can be inserted into the slotted handle of a pedicle screw instrument which fits the dimensions of the RJB device. A set of compatible handles and instruments are provided with the RJB system; each instrument is manufactured with a slot feature at the end of the handle, allowing for the RJB device to be inserted and held in place via friction fit. The RJB device is marked with orientation arrows to ensure proper insertion into a compatible handle.

The RJB operates by sensing the axial and sagittal angles that the device is oriented in with respect to gravity and outputting those angles to the tablet display for the user to view. Angles are displayed to either whole or half-degree precision. The measurements are made with respect to gravity and do not have any anatomical reference.

RJB Application

The RJB Application (App) is the user interface of the system. The user will connect the RJB device to the RJB App upon start-up of the application via a welcome screen that contains a text box for device serial number input or barcode scanning. Following pairing, the RJB device can then be inserted into the compatible slotted handle of a pedicle screw instrument.

Through the App, the user can rename or remove the paired device depending on need. Up to four RJB devices can be paired at once. During the pairing process, the user will be required to choose a preset name for the device or can choose to manually type in a custom name not on the list. After pairing, the user can choose which device to have selected when the selected device's data is communicated to the application. The RJB App will display the axial and sagittal angles on the touchscreen display. While using connected devices, users also have the option to hold desired angles on screen or offset the displayed angle by a desired amount through the App.

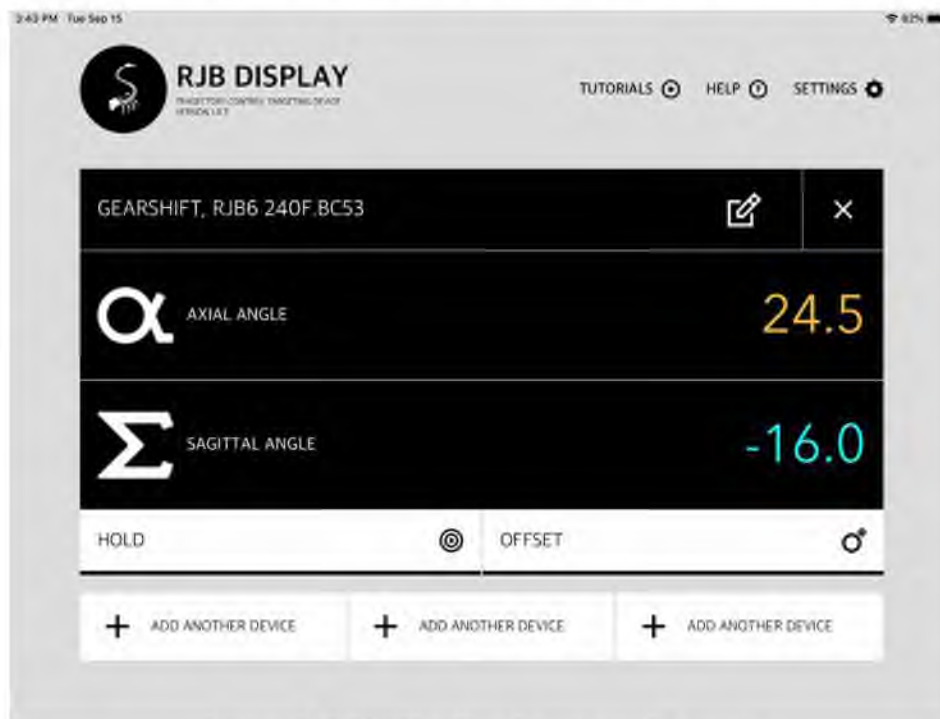


Figure 2: RJB Application example screen

SUMMARY OF NON-CLINICAL TESTING

BIOCOMPATIBILITY / MATERIALS

The RJB is intended to be used with lumbosacral pedicle screw instrumentation, inserted into the handle end of an instrument which does not contact the patient during the surgical procedure. The device is thus considered a non-contact device per *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within risk management process"*, having no direct or indirect contact with the body.

The outer material of the RJB is (b)(4) polyolefin heat shrink tubing printed with (b)(4). This commercial-grade heat shrink material is RoHS-compliant and is lead- and halogen-free. Although not required for non-contact devices, cytotoxicity testing per ISO 10993-5 was performed on samples of the heat shrink tubing material that had undergone the same handling, cleaning, and sterilization processes as production devices.

All patient-contacting instrumentation provided with the RJB system is manufactured from medical grade stainless steel per ASTM F899 and 6061-T6/T651 aluminum per ASTM B211 or B221 with a type and duration of patient contact of direct tissue/bone contact, limited (≤ 24 hours) duration. Biocompatibility evaluation has been completed per *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within risk management process"*.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The following electromagnetic compatibility and electrical safety testing was performed for the RJB:

- Electromagnetic compatibility testing per:
 - IEC 60601-1-2:2014
 - FCC CFR 47, Part 15, subpart B:2017, Class A (radiated emissions)
 - AIM 7351731 Rev. 2.00 (2017-02-23) (electromagnetic immunity)
 - IEEE/ANSI C63.27.2017 (coexistence/crosstalk)
- Electrical safety testing per:
 - IEC 60601-1:2005, AMD1:2012

As part of the compliance to IEC 60601-1, the RJB risk management documentation was assessed in conformance with ISO 14971:2007 Medical devices – Application of risk management to medical devices. Also, as part of IEC 60601-1 testing, the RJB firmware documentation was assessed in conformance with IEC 62304:2006 Medical device software — Software life cycle processes. Upon completion of the electromagnetic compatibility and electrical safety testing, all relevant portions met the acceptance criteria and the labeling mitigations have been implemented.

For additional information regarding electromagnetic compatibility and electrical safety, please see the Surgical Technique.

SOFTWARE / CYBERSECURITY

The RJB software documentation and verification testing is based on a Level of Concern of Moderate per FDA's [*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*](#). Prior to mitigation of hazards, a failure of the software device could result in minor injury to the patient. The device and labeling passed all relevant portions of the testing.

Software Description

The programmable software that comprises the RJB takes two forms, 1) programmed firmware loaded onto the integrated chip on the RJB device itself, and 2) the software of the RJB App run on a tablet.

The programmed firmware allows the RJB hardware to measure angular displacement from vertical by using a Micro Electro-Mechanical System (MEMS) accelerometer to measure the gravitational field in all three axes. The three gravitational measurements are converted into angles by basic trigonometry. The displacement angles are then communicated to a display device (RJB App run on a tablet) by a BLE wireless link. An integrated microprocessor and RF radio module are used to control the accelerometer, compute the angles, and send the results to the display device.

The App connects to an RJB device via either manual serial number entry or automated barcode scanning. Once paired, the App displays the axial and sagittal angles communicated by the RJB onto the tablet screen.

Verification Testing

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

1. Identify software requirement specifications.
2. Create a verification test procedure and acceptance criteria for each specification.
3. Perform each verification test and record the results.
4. Testing is considered complete once all test procedures have successfully passed, which indicates that all functions of the RJB system are properly implemented.

Following completion of the verification testing, all software features have passed the testing acceptance criteria.

Revision Level History

The current revision of the RJB firmware is version 3.0, and the current revision of the RJB App is v1.0.9. These versions of the firmware and software were used to conduct system level verification/validation.

Cybersecurity

Adequate risk analyses and information per FDA guidance [*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*](#) were provided. The cybersecurity risks associated with the RJB were evaluated through the following:

- Identification of assets, threats, and vulnerabilities;
- Assessment of the impact of threats and vulnerabilities on device functionality and end user/patients;
- Assessment of the likelihood of a threat and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk and risk acceptance criteria.

The cybersecurity risk analysis performed, the controls identified, the comparison with the National Vulnerability Database, and the labeling information detailed within the Cybersecurity Assessment demonstrated that all risks associated with network capable interfaces of the device have been mitigated to the lowest possible level.

PACKAGING, STERILIZATION, AND SHELF LIFE

RJB Device

The RJB device is provided sterile for single use. The sterilization method of the device has been validated in accordance with ISO 11135:2014 to ensure a Sterility Assurance Level (SAL) of 10^{-6} before the device is marketed.

Each Ruthless Spine RJB device has a shelf life of 1 year, which has been validated through real-time and accelerated aging techniques per ASTM F1980-16. The shelf life of the ethylene oxide (EO)-sterilized packages was verified by demonstrating package integrity through gross leak detection and peel strength testing.

RJB Instruments

RJB instruments and handles are provided visually clean and non-sterile and must be sterilized prior to use. None of the provided instruments or handles are reusable. Steam sterilization method per ANSI/AAMI/ISO 17665-1 was validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} .

PERFORMANCE TESTING-BENCH

The RJB underwent a series of non-clinical performance tests described below to verify safety and effectiveness during use, as well as to validate the overall device design.

Angle Measurement Accuracy

In order to verify the system-level angle measurement accuracy of the RJB device, the angular outputs of the device were compared with a NIST-traceable calibrated digital

protractor mounted at the same axial or sagittal angle in space as the RJB device. All test results met the acceptance criteria.

Table 1: System-Level Angle Measurement Accuracy Testing Results

	Axial Orientation	Sagittal Orientation
Average Difference Between RJB and Protractor Measurement \pm standard deviation	$0.36 \pm 0.32^\circ$	$0.74 \pm 0.47^\circ$

Battery Life Testing

Battery life testing was performed following distribution and accelerated aging validation to confirm that these activities do not adversely affect the RJB's 8-hour usage life. All devices demonstrated a battery life of 8 hours, meeting the acceptance criterion.

Procedural Accuracy Testing

Procedural accuracy testing of the RJB device was performed in order to validate the accuracy of the device under simulated use conditions. The test method involved the user positioning the RJB instrument against a cadaver pedicle to simulate pedicle screw placement. The instrument was positioned in a composite angle using a pre-planned axial angle from MRI imaging and sagittal angle from fluoroscopy imaging. When the instrument was positioned at the desired composite angle, both a fluoroscopic and a pair of photographic images were taken of the instrument to allow for angle calculation following the test. The images taken were used to calculate composite angle error as compared to the ground-truth measurement (gravity).

The results for angular composite error for all 240 trials (3 measurements at each of 5 levels for 16 surgeon users) is shown below are presented in Figure 3 below.

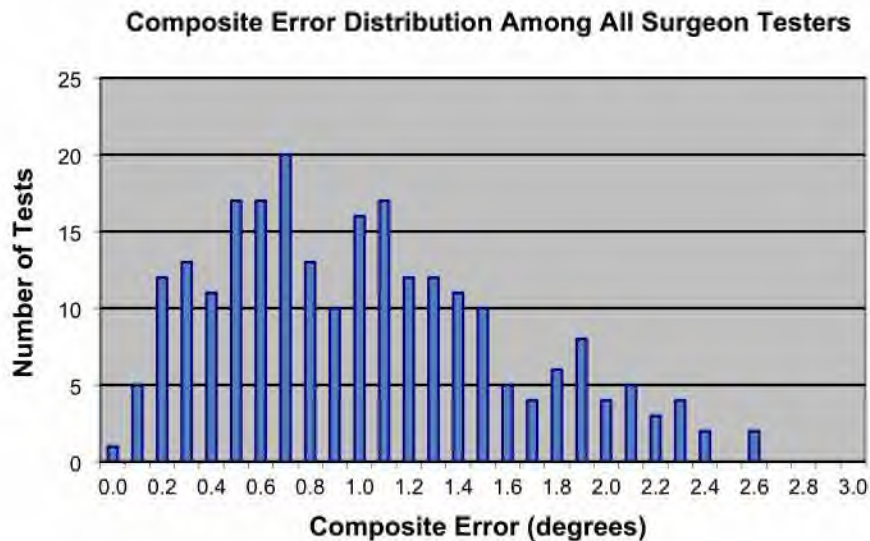


Figure 3: Angular composite error for all trials

Repeatability of the fluoroscopic angles was computed from the difference between the largest and smallest fluoroscopic sagittal angle at each level. The results are summarized in Figure 4.

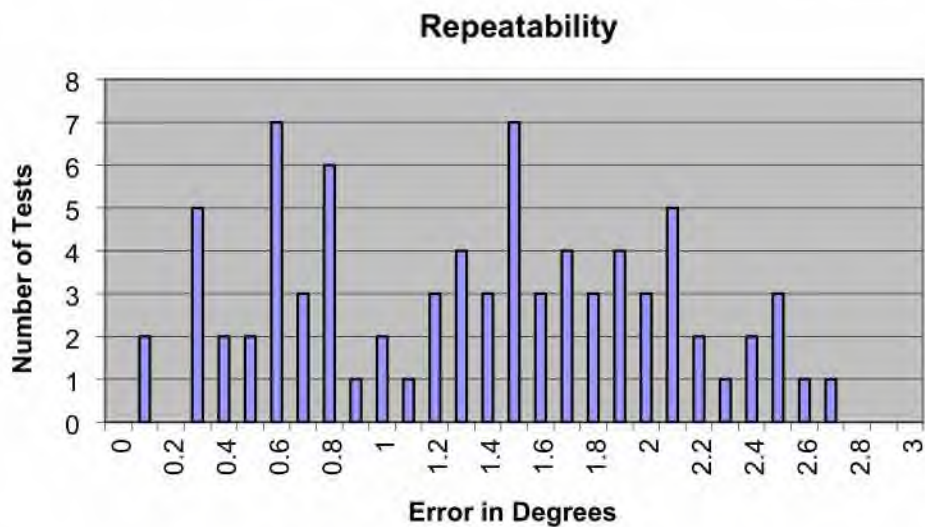


Figure 4: Fluoroscopic angle repeatability results

All sixteen (16) surgeons participating in the tests met the acceptance criteria. None of the composite errors exceeded 2.6 degrees ($\pm 3^\circ$ acceptance criteria) and the largest fluoroscopic image repeatability deviation was 2.7 degrees ($\pm 3^\circ$ acceptance criteria).

USABILITY TESTING

Usability testing in the form of a surgeon evaluation of the RJB device was performed to validate the design of the RJB device and application. The test was also intended to determine the effectiveness of device labeling in instructing the users on proper device setup and operation. Surgeon feedback was captured with a Usability Test Questionnaire following the test. Each question was asked with response options given either as a scale of 1-5 (strongly disagree to strongly agree), a yes/no chosen response, or a written response as prompted. See Table 2 below for a summary of the questionnaire results.

Table 2: Usability Test Questionnaire Results

Item	Question	Avg Score/Summary	
1	The RJB device fit securely into the instrument handle.	5	
2	The battery pull tab was easy to remove.	5	
3	Which pairing method was used?	Barcode: 14	Manual: 1
4	It was easy to pair the RJB device.	5	
5	Four (4) RJB devices were able to pair.	Yes: 13	No: 1
6	The RJB for the instrument in use was always displayed on the screen.	Yes: 15	No: 0
7	The Hold feature held the angle on-screen and did not remove the held angle until 'Clear Hold' was pressed.	Yes: 14	No: 1
8	The Offset feature offset the angle on-screen and did not remove the offset until 'Clear Offset' was pressed.	Yes: 14	No: 1
9	The RJB device remained on for the entire test.	Yes: 14	No: 1
10	The angles updated in real-time throughout the test.	Yes: 14	No: 1
11	The angles displayed were in the proper plane.	Yes: 14	No: 1
12	The device labeling was clear and helpful.	5	
13	The measurement accuracy of the RJB is ± 3.5 degrees in both the axial and sagittal directions.	4.9	
14	Overall, I found the various features of the RJB device and application to be well-integrated.	4.9	
15	I would imagine that most people would learn to use the RJB device very quickly.	4.7	

Overall, surgeons representing potential clinical users provided valuable input on the usability of the RJB device. No feedback warranted device design or labeling changes. The testing validated that the user needs are met with the current device design and labeling.

LABELING

The RJB system labeling consists of the following: device description, device characteristics, wireless technology information, indications for use, contraindications, warnings and precautions, cleaning and sterilization information, storage and handling information, tablet and app installation instructions, device operating instructions, product complaint information, and

label symbols definitions. The labeling meets the requirements of 21 CFR 801.109 for prescription devices and specifically indicates that the device is not intended to replace a surgeon’s clinical judgement nor intended to influence clinical decision-making. The sterile packaging section includes information on the shelf life of the device.

RISKS TO HEALTH AND IDENTIFIED MITIGATION MEASURES

Table 3 identifies the risks to health that may be associated with the use of an intraoperative surgical angle measurement guide and the measures necessary to mitigate these risks.

Table 3 – Identified Risks to Health and Mitigation Measures

Risks to Health	Mitigation Measures
Implant malpositioning, prolonged operative time, or loss of function / measurement integrity resulting from user error, measurement inaccuracy, and/or hardware failure	Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization/reprocessing validation Shelf life testing Labeling
Implant malpositioning, prolonged operative time, or loss of function / measurement integrity resulting from software error	Software verification, validation, and hazard analysis Usability testing Labeling
Electrical shock	Electrical safety testing Labeling
Device failure due to interference from other devices, or interference leading to failure of other devices in the operating environment	Electromagnetic compatibility/interference testing Wireless coexistence testing Electrical safety testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, an intraoperative surgical angle measurement tool is subject to the following special controls:

- (1) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of system-level accuracy and validation of procedural accuracy in simulated use.
- (2) Usability testing must demonstrate that the intended user(s) can correctly use the device based on the instructions for use.

- (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 device.
- (5) Software verification, validation, and hazard analysis must be performed.
- (6) Performance data must demonstrate the electrical safety, electromagnetic compatibility, and wireless coexistence of the device.
- (7) Labeling must include:
 - (i) A detailed summary of the device technical parameters;
 - (ii) Information regarding limitations of the clinical significance of the device output;
 - (iii) A detailed summary of the accuracy and precision of the device;
 - (iv) Validated methods and instructions for reprocessing of any reusable components; and
 - (v) The shelf life of the device.

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., providing intraoperative measurements on the orientation of pedicle screw instrumentation relative to gravity). System-level accuracy verification and simulated-use procedural accuracy validation demonstrated that the accuracy of the angle measurements provided by the device are acceptable for the intended use of the RJB in lumbosacral pedicle screw procedures.

Although no clinical benefit has been demonstrated or is claimed, the sponsor's system, procedural, and usability testing indicate that adequately trained surgeons can use the RJB device to accurately measure the isolated or composite sagittal and axial angles of surgical instruments designed for lumbosacral pedicle screw implantation ($\pm 1^\circ$ system / $\pm 3^\circ$ procedural).

Accordingly, the submitted test results demonstrate that an informed and adequately trained surgeon can accurately and reproducibly use the Ruthless Spine RJB to determine the axial and sagittal trajectory angles of the instruments relative to a vertical plumb line in line with gravity. These measurements may be of value during the intra-operative implantation of lumbosacral pedicle screws when used in adjunct to traditional radiographic, visual, and tactile methods.

The risks of the device are based on the risk analysis performed and include loss of function or measurement integrity resulting from user error, measurement inaccuracy, and/or hardware or software failure, adverse tissue reaction, infection, or electromagnetic interference. Types of harmful risks include patient harm due to incorrect instrument trajectory, such as implant malpositioning. Associated device risks (e.g., patient harm due to incorrect instrument trajectory, prolonged operative time, surgeon distraction, and/or electrical shock) can be effectively mitigated by training and the use of general and special controls.

Patient Perspectives

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

Benefit/Risk Conclusion

In conclusion, based on the available data, when used as an intraoperative tool for measuring the angle of pedicle screw instruments in two planes relative to the vertical gravity plumb line, the probable benefit of the Ruthless Spine RJB outweighs the probable risk when the device is used as intended. Overall, the device provides benefits, and the identified risks can be mitigated by the use of general controls and identified special controls.

CONCLUSION

The De Novo request for the Ruthless Spine RJB is granted and the device is classified under the following:

Product Code: QWL

Device Type: Intraoperative surgical angle measurement tool

Class: II

Regulation: 21 CFR 888.4560