November 29, 2024

Ruthless, LLC dba Ruthless Spine
% Kyle Kovach
Sr. Quality and Regulatory Engineer
JALEX Medical, LLC
27865 Clemens Road
Westlake, Ohio 44145

Re: K243375
Trade/Device Name: Ruthless Spine RJB
Regulation Number: 21 CFR 888.4560
Regulation Name: Intraoperative Surgical Angle Measurement Tool
Regulatory Class: Class II
Product Code: QWL
Dated: October 30, 2024
Received: October 30, 2024

Dear Kyle Kovach:

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, 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)*

K243375

Device Name

Ruthless Spine RJB

Indications for Use *(Describe)*

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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

RUTHLESS SPINE

510(k) Summary

Applicant:	Ruthless, LLC dba Ruthless Spine 1438 Arrow Highway Ste F Irwindale, CA 91706
Date:	10/30/2024
Contact Person:	Kyle Kovach, Sr. Quality and Regulatory Engineer
Contact Telephone:	(440) 787-5832
Contact Fax:	(440) 933-7839

Device Trade Name:	**Ruthless Spine RJB**
Common Name:	Intraoperative Surgical Angle Measurement Tool
Device Classification Name:	21 CFR 888.4560
Device Class:	II
Reviewing Panel:	Orthopedic
Product Code:	QWL
Primary Predicate Device:	**DEN230012 – Ruthless Spine RJB**

Device Description:
The Ruthless Spine 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
- Straight Probe
- Duckbill Probe
- RJB Application

Note, a Tablet Computer is required to operate the device. The Tablet is not provided to the end user.

RUTHLESS SPINE

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.

Description of Modifications:

The Ruthless Spine RJB instruments were modified from single-use disposable to reusable. There have been no changes to the RJB or RJB software application.

Summary of Technological Characteristics

The subject Ruthless Spine RJB has the same intended use, indications for use, and technological characteristics as the predicate system.

Item	Subject Device	Predicate Device	Equivalence
	Ruthless Spine RJB	Ruthless Spine RJB (DEN230012)	
Classification Name	Intraoperative Surgical Angle Measurement Tool	Intraoperative Surgical Angle Measurement Tool	Identical
Regulation	21 CFR 888.4560	21 CFR 888.4560	Identical
Product Code	QWL	QWL	Identical
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.	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.	Identical
Device Description	The Ruthless Spine RJB device is an intraoperative surgical angle measurement guide that attaches to surgical instruments to measure the angle of the instrument	The Ruthless Spine RJB device is an intraoperative surgical angle measurement guide that attaches to surgical instruments to measure the angle of the instrument	Identical

RUTHLESS SPINE

Item	Subject Device	Predicate Device	Equivalence
	Ruthless Spine RJB	**Ruthless Spine RJB (DEN230012)**	
	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 • Straight Probe • Duckbill Probe • RJB Application Note, a Tablet Computer is	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 • Straight Probe • Duckbill Probe • RJB Application Note, a Tablet Computer is	

RUTHLESS SPINE

Item	Subject Device	Predicate Device	Equivalence
	Ruthless Spine RJB	**Ruthless Spine RJB (DEN230012)**	
	required to operate the device. The Tablet is not provided to the end user.	required to operate the device. The Tablet is not provided to the end user.	
Instrument Materials	Stainless steel, aluminum	Stainless steel, aluminum	Identical
Sterilization Methods	Ethylene oxide, steam	Ethylene oxide, steam	Identical

Performance Testing – Non-Clinical:
There were no changes to the design, intended use, or principles of operation. Therefore, performance testing was not required. The predicate device performance data is applicable to the subject device.

Performance Testing – Clinical:
Clinical testing was not applicable to support a substantial equivalence determination for the subject device.

Conclusion
Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.