July 14, 2023

Ruthless, LLC dba Ruthless Spine
% Kyle Kovach
Sr. Quality and Regulatory Engineer
JALEX Medical
27865 Clemens Road, Suite #3
Westlake, Ohio 44145

Re: DEN230012
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: February 16, 2023
Received: February 16, 2023

Dear Mr. Kyle Kovach:

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 Ruthless Spine RJB, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Ruthless Spine RJB, and substantially equivalent devices of this generic type, into Class II under the generic name Intraoperative surgical angle measurement tool.

FDA identifies this generic 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.

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 February 16, 2023, FDA received your De Novo requesting classification of the Ruthless Spine RJB. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Ruthless Spine RJB 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 Ruthless Spine RJB 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:

| **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<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation |
| Infection | Sterilization/reprocessing validation<br>Shelf life testing<br>Labeling |
| Implant malpositioning, prolonged operative time, or loss of function / measurement integrity resulting from software error | Software verification, validation, and hazard analysis<br>Usability testing<br>Labeling |
| Electrical shock | Electrical safety testing<br>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<br>Wireless coexistence testing<br>Electrical safety testing<br>Labeling |

In combination with the general controls of the FD&C Act, the 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.

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

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.

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 surgical angle measurement tool they intend to market prior to marketing the device.

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/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 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/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).

If you have any questions concerning the contents of the letter, please contact Tejen D. Soni at 240-402-9872.

Sincerely,

for Vincent J. Devlin -S

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health