



November 25, 2025

Medusa Orthopedics, LLC  
Penny Rasmussen  
Consultant  
8500 Belcher Road N  
Apt. 807  
Pinellas Park, Florida 33781

Re: K252555

Trade/Device Name: Medusa Orthopedics Boa External Fixation System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: KTT  
Dated: October 28, 2025  
Received: October 28, 2025

Dear Penny Rasmussen:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Lixin Liu-S**

Lixin Liu, Ph.D

Assistant Director

DHT6A: Division of Joint Arthroplasty Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K252555

Device Name

Medusa Orthopedics Boa External Fixation System

Indications for Use (Describe)

The Medusa Orthopedics Boa External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects.

The Medusa Orthopedics Boa External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

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.**

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Traditional 510(k) Medusa Orthopedics Boa External Fixation System

**510(k) Summary**  
**Medusa Orthopedics Boa External Fixation System**

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901-317-9752

**Trade Name:** Medusa Orthopedics Boa External Fixation System

**Common Name:** External Fixation Frame

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3030

**Panel:** Orthopedic

**Product Code:** KTT

**Device Description**

The Medusa Orthopedics Boa External Fixation System is a ring fixator device used to stabilize and maintain alignment of complicated bone fractures, soft tissue and/or congenital deformity repairs of an extremity. The fixator consists of two rings connected by four (4) struts that are lengthened and shortened independently. It is a modular system and facilitates a multitude of frame configurations to provide a wide variety of patient needs. The independent motion of the struts allows the surgeon to adjust the position of the proximal and distal rings. By utilizing the body's natural ability of osteogenesis to grow new bone tissue, the system guides the orientation and position of the new bone to the desired corrected location in a steady controlled manner.

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

**Indications For Use/Intended Use**

The Medusa Orthopedics Boa External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The Medusa Orthopedics Boa External Fixation System is for use on all long bones including tibia, fibula, femur, humerus, radius and ulna.

**Predicate**

The Subject Medusa Orthopedics Boa External Fixation System components are substantially equivalent with respect to the materials, design and indications for use to the following device, previously cleared by the FDA:

**Predicate:**

- DNE External Fixation System – K113106

**Technological Characteristics Comparison**

The subject components for the Medusa Orthopedics Boa External Fixation System are substantially similar to the DNE External Fixation system (K113106).

The Medusa Orthopedics Boa External Fixation System is substantially equivalent to the predicate device in indications for use, design, operational principles and materials.

The proposed subject device has the same intended use and similar technological characteristics to the predicate. Any differences do not raise different questions of safety and effectiveness, and the proposed device is at least as safe and effective as the legally marketed predicate device. The Subject and Predicate devices are listed below in **Table 1**.

**Table 1. Comparison of Subject and Predicate Device**

	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Comparison</b>
Device	Medusa Orthopedics Boa External Fixation System	D.N.E. External Fixation System	
Manufacturer	Medusa Orthopedics, LLC	D.N.E., LLC.	
510(k) Number	K252555	K113106	

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

FDA Product Code	KTT	KTT	Same
Regulatory Class	II	II	Same
Regulation Number	888.3030	888.3030	Same
Intended Use / Indications for Use	<p>The Medusa Orthopedics Boa External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects.</p> <p>The Medusa Orthopedics Boa External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.</p>	<p>The D.N.E. External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects.</p> <p>The D.N.E. External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.</p>	<p>The patient population is the same for the intended use /indications for use.</p> <p>The subject and predicate systems have the same intended use /indications for use.</p> <p>No new or increased risks identified.</p>
Anatomical Sites	Long bones including tibia, fibula, femur, humerus, radius and ulna.	Same	The anatomical sites are the same for the subject and predicate.

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

			No new or increased risks identified.
Material	Aluminum, Ti 6061 and Stainless Steel and PEEK.	Same	The materials in the subject system are the same as the predicate. The materials are commonly used in many orthopedic devices currently on the market. No new or increased risks identified.
Principle of Operation	The Medusa Orthopedics Boa External Fixation System consists of the following elements: (1) bridge elements (2) anchor elements (3) connector elements. The Medusa Orthopedics Boa External Fixation System design allows freedom of wire and pin placement, ease of assembly, stable fixation of bone	Same	Same. No new or increased risks identified.
MRI	The Medusa Orthopedics Boa External Fixation System has not been evaluated for safety and compatibility in the MRI environment.	Same	Same. No new or increased risks identified.
Single Use	Bridge, Anchor and Connector Elements are single use.	Same	Same. No new or increased risks identified.

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

Reusable	Instruments are reusable and End User Sterilized.	Same	<p>The subject and the predicate instruments are common components for orthopedic procedures. The subject and predicate instruments are general and not unique to the system.</p> <p>The instruments have the same requirements for cleaning and end user sterilization.</p> <p>No new or increased risks are identified.</p>
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Bridge elements, anchor elements, and connector elements for the Medusa Orthopedics Boa External Fixation System are the same or similar in dimensions and materials as the D.N.E. Predicate device. The Technological Characteristics Comparisons for the Bridge Elements are listed below in **Table 2**.

**Table 2.**

Bridge Elements			
Name	Subject	Predicate	Comments
Rings	<p>The Medusa Orthopedics Boa External Fixation System rings are 8 mm thick and are provided in the following diameters: 140 mm, 160 mm, 180 mm, and 200 mm.</p> <p>The material used is 6061 Aluminum</p>	<p>D.N.E. rings are 8 mm thick and are provided in the following diameters: 140 mm, 160 mm, 180 mm, and 200 mm.</p> <p>The material used is 6061 Aluminum</p>	There are no dimensional or material differences between the ring components.
Struts	Struts are 0.5-inch in thickness and are offered in the following lengths: 35 mm, 50 mm,	Struts are 0.5-inch in thickness and are offered in the following lengths: 35 mm,	

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

	75 mm, 100 mm, and 150 mm. The material is 6061 Aluminum	50 mm, 75 mm, 100 mm, and 150 mm. The material is 6061 Aluminum	
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The Technological Characteristics Comparisons for the Anchor Elements are listed below in **Table 3**.

**Table 3.**

<b>Anchor Elements</b>			
<b>Name</b>	<b>Subject</b>	<b>Predicate</b>	<b>Comments</b>
Pins	4mm, 5mm and 6mm half pins.  Thread Length 45MM Total Length 180MM  316LVM Stainless Steel	4mm, 5mm and 6mm half pins.  Thread Length 45MM Total Length 180MM  316LVM Stainless Steel	Medusa Orthopedics Boa External Fixation System and the predicate anchor elements are sourced from the same supplier. There are no differences between material or dimensions.
Wires	Wires are 2.0 mm in diameter and composed of 316L stainless steel.	Wires are 2.0 mm in diameter and composed of 316L stainless steel.	There are no differences between material or dimensions.

The Technological Characteristics Comparisons for the Connector Elements are listed below in **Table 4**.

**Table 4.**

<b>Connector Elements</b>			
<b>Name</b>	<b>Subject</b>	<b>Predicate</b>	<b>Comments</b>
Bolts- Half Pin	Half Pin 12mm,16mm,20mm and 25mm .500" diameter 17-4 SS	Half Pin 12mm,16mm,20mm and 25mm .500" diameter 17-4 SS	The Subject and Predicate wire and half-pin fixation bolts utilize the same M6 × 1 thread and are manufactured from 17-4 stainless steel, same as the predicate.
Wires	Wires .920" Length .500" diameter. 17-4 SS	Wires .920" Length .500" diameter. 17-4 SS	

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Hex Nut –	Hex Nut – 10mm length, .390” diameter and 316 SS	Hex Nut – 10mm length, .390” diameter and 316 SS	The Subject and Predicate have the same dimensions and material.
Lock Nut	Lock Nut – 10mm length, .390” diameter and 316 SS and nylon	Lock Nut – 10mm length, .390” diameter and 316 SS and nylon	
Fang Clamp	2 ¼” Length ¾” Height  Aluminum 7075, 17-4 SS	Plates 2 and 4 holes. .500” diameter 17-4 SS	Similar to the predicate. The Fang Clamp is used in the same manner as the predicate’s plates. A clamp or plates is used when a doctor wants to size down the rings. Normally a larger proximal ring and a smaller distal ring are used. (Heavier calf and smaller ankle).  Testing showed that the fang clamp was stronger than a plate.
Plates	Plates 2 and 4 holes. .500” diameter 17-4 SS		
Washers	Round Washer Flat Washer Slotted Washer 316 SS	Round Washer Flat Washer Slotted Washer 316SS	The Subject and Predicate are the same.

The information provided within this section demonstrates that the proposed Medusa Orthopedics Boa External Fixation System has the same intended use and indications for use as the legally marketed predicate device. The Subject and Predicate systems are similar in technological characteristics such as materials, design and application. The systems both apply the same established surgical techniques for repair of fractures or deformities utilizing a ring fixation system.

In addition, the comparison provides justification that no different questions of safety and effectiveness have been raised due to any differences, and the proposed device is at least as safe and effective as the legally marketed predicate device.

## Traditional 510(k) Medusa Orthopedics Boa External Fixation System

**Performance Testing**

Mechanical testing and engineering analysis were conducted on the Medusa Orthopedics Boa External Fixation System to demonstrate substantial equivalence to the Predicate system.

The objective of this test battery was to characterize the Medusa External Boa Fixation System mechanical properties in Fatigue Axial Load Testing in accordance with ASTM F1541-17 Annex 7 to estimate the maximum run out force value at 1 000 000 cycles.

The assembled constructs were rigidly mounted in the test frame using self-leveling spacer jacks placed around the device approximately 90° apart accompanied with toe clamps tightened directly over the spacer jacks. The self-leveling spacer jacks were used to prevent stress risers and keep the long-axis of the device aligned with the test frame actuator axis.

The fatigue testing was to simulate how an external fixation is loaded in real life through weight bearing and ambulation. The test demonstrates that the rigidity of the Subject device's entire construct does not differ from the Predicate's design. The Medusa Orthopedics Boa External Fixation System achieved 1,000,000 cycles at 1975N, whereas the Predicate's runout at 1,000,000 cycles achieved 1350N.

**Conclusion**

The Medusa Orthopedics Boa External Fixation System is shown to be substantially equivalent to its Predicate, DNE External Fixation System. The subject device has similar intended uses, indications, technological characteristics, and principles of operation as the predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, performance data demonstrates no different questions of safety or effectiveness. Thus, Medusa Orthopedics Boa External Fixation System is substantially equivalent with the predicate.