January 20, 2026

Blue Ocean Global
% Danielle Short
Regulatory Consultant
MEDIcept, Inc.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K253291
Trade/Device Name: Excelsior 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: December 17, 2025
Received: December 18, 2025

Dear Danielle Short:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.01.20 14:24:18 -05'00'

For 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

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)*

K253291

Device Name

Excelsior System

Indications for Use *(Describe)*

The Excelsior External Fixation System is indicated for adult and pediatric (greater than 2 through 21 years of age) patients for the treatment and fixation of:
• Open and closed fractures
• Post-traumatic joint contracture which has resulted in loss of range of motion
• Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
• Pseudoarthrosis, infected union, non-union, or malunion of long bones
• Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
• Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
• Correction of segmental bony or soft tissue defects
• Joint arthrodesis
• Management of comminuted intra-articular fractures
• Bone transport

The Excelsior External Fixation System is indicated in adults for:
• Osteotomy
• Revision procedure where other treatments or devices have been unsuccessful
• Bone reconstruction procedures
• Fusions and replantations of the foot
• Charcot foot reconstruction
• Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
• Lisfranc dislocations
• Ankle distraction (arthrodiastasis)
• Septic fusion

The Excelsior Translation Device is not intended for weight bearing applications. Patients must remain non weight bearing on the Excelsior External Fixation frame when the Excelsior Translation Device is used for transport applications.

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.

510(k) Summary

DATE PREPARED
January 16, 2026

MANUFACTURER AND 510(k) OWNER
Blue Ocean Global
12550 Biscayne Boulevard, Suite 110
Official Contact: Scott Ludecker, President and CEO

REPRESENTATIVE/CONSULTANT
Danielle Short, Regulatory Consultant
MEDIcept
Telephone: (610)-304-4614
Email: dshort@medicept.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Excelsior System
Common Name:	Multilateral Fixator Components
Regulation Number:	888.3030
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories.
Class:	II
Product Code:	KTT
Review Panel:	Orthopedic Devices

PREDICATE/REFERENCE DEVICE IDENTIFICATION

510(k) Number	Predicate/ Reference Device Name	Predicate/Reference
K232838	Monkey Rings External Fixation System	Primary Predicate
K201253	TAYLOR SPATIAL FRAME External Fixator	Secondary Predicate
K202833	Sequel External Fixation Device	Secondary Predicate
K151580	D.N.E. External Fixation System	Reference
K181630	Revolution External Fixation System	Reference

DEVICE DESCRIPTION
The Blue Ocean Global Excelsior System is a single-use modular external fixator consisting of implantable half pins and fixation wires and non-patient contact rings, telescoping struts, telescoping rods, threaded rods, posts, hinges, connection plates, twisted plates, threaded sockets, bolts, washers and nuts that are combined by the health care professional to construct different frame configurations based on patient anatomy and indicated use. The frame forms the support metalwork for the torsion wire used in fracture fixation and several other indications for long bone fixation procedures. Special wrenches and accessories are included for the proper assembly of the components. The system is manufactured from stainless steel, aluminum, and titanium.

INDICATIONS FOR USE

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- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
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- Septic fusion

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Blue Ocean Global believes that the Excelsior System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use and same technological characteristics as the predicate devices. The devices are designed as modular, ring-based external fixation systems, tested to standard ASTM F1541. The additional components compared to the primary predicate are substantially equivalent to the components in the secondary predicates. The addition of these components does not raise different questions of safety or effectiveness. The performance testing results demonstrate that the device continues to meet all specifications and requirements that were met by the predicate devices. The subject device can be found substantially equivalent to the predicate devices.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Excelsior System. The following tests were performed to demonstrate safety based on current industry standards:

- Standard Specification and Test Methods for External Skeletal Fixation Devices per ASTM F1541.
- Sterilization Validation
- Dry Time Validation
- Cleaning and Disinfection Validation

The results of these tests indicate that the Excelsior System is substantially equivalent to the predicate devices.

CONCLUSION

The Excelsior System is considered substantially equivalent to the predicate devices. It can be concluded that the subject device does not raise different issues of safety or efficacy compared to the predicate devices.