November 16, 2020

Crystal Higgenbottom-Shaffer
Regulatory Affairs Specialist I
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K202762
Trade/Device Name: Circular Fixation with Balanced Cable Transport
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: September 15, 2020
Received: September 21, 2020

Dear Crystal Higgenbottom-Shaffer:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202762

Device Name

Circular Fixation with Balanced Cable Transport

Indications for Use *(Describe)*

External fixation devices are used on adults or pediatric patients as required. External fixation systems consist of various components that are used to build fixator assemblies unique to the patient's needs. These devices are modular therefore, a multitude of different fixator frame configurations are possible. External fixation devices are used for the following indications:

1. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
2. Open and closed fracture fixation
3. Pseudoarthrosis of long bones
4. Limb lengthening by distraction (not applicable for use with COMPASS Universal Hinge)
5. Correction of bony or soft tissue deformities (not applicable for use with COMPASS Universal Hinge).
6. Joint arthrodesis (not applicable for use with COMPASS Universal Hinge)
7. Infected fractures
8. Nonunions

The indications for use listed above cover many of the external fixation systems marketed by Smith & Nephew. These indications are similar to the indications of the predicate devices. The device is intended for single use.

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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510(k) SUMMARY

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	September 15, 2020
Contact Person:	Crystal Higgenbottom-Shaffer, Regulatory Affairs Specialist I T (901) 800-3364 M (901) 832-2616
Name of Device:	Circular Fixation with Balanced Cable Transport
Common Name:	External Fixation System
Device Classification Name and Reference:	21 CFR 888.3030- Single/multiple component metallic bone fixation appliances and accessories- Class II
Device Class:	Class II
Panel Code:	Orthopedic/87
Product Code:	KTT
Predicate Device:	ILIZAROV Pulley System – K042436 The predicate device has not been subject to a design related recall.

510(k) SUMMARY

Device Description:

The subject of this Traditional 510k is the Circular Fixation with Balanced Cable Transport. Originally, the subject device was identified as the ILIZAROV with Balanced Cable Transport. It has since been decided as a company's decision to change the name of the subject device to Circular Fixation with Balanced Cable Transport. In addition, there was an update to the indications for use language since the Pre-Submission. The subject Circular Fixation with Balanced Cable Transport is a product line addition to the predicate, ILIZAROV Pulley System. The Circular Fixation with Balanced Cable Transport consists of cables, pulleys, and the new subject devices, the struts. The existing cables and pulleys are cleared on a similar external fixation system, the predicate ILIZAROV Pulley System, via premarket notification K042436 S.E. 10/07/2004. In the subject, Circular Fixation with Balanced Cable Transport, the cable is routed through the bone segment and exits through soft tissue. Cables are available in diameter of 1.8mm and a length of 1200mm. The subject telescopic rod or a modified strut acting as a motor is attached to the ring-based circular fixation construct. The subject device is turned to pull the cable and move the bone segments in order to perform bone transport and limb lengthening. The advantages of using the subject Circular Fixation with Balanced Cable Transport, include the ability to use fewer half pins and wires. Fewer half pins and wires will create less soft tissue disruption, eliminating the need to pull pins and wires through the skin and soft tissue as the bone moves.

510(k) SUMMARY

Intended Use

External fixation devices are used on adults or pediatric patients as required. External fixation systems consist of various components that are used to build fixator assemblies unique to the patient's needs. These devices are modular therefore, a multitude of different fixator frame configurations are possible. External fixation devices are used for the following indications:

1. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
2. Open and closed fracture fixation
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6. Joint arthrodesis (not applicable for use with COMPASS Universal Hinge)
7. Infected fractures
8. Nonunions

The indications for use listed above cover many of the external fixation systems marketed by Smith & Nephew. These indications are similar to the indications of the predicate devices. The device is intended for single use.

510(k) SUMMARY

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject device, The Circular Fixation with Balanced Cable Transport, is substantially equivalent to the below listed legally marketed predicate device with regard to intended use, material, and performance characteristics. The design of the subject Circular Fixation with Balanced Cable Transport system is relatively similar to the predicate ILIZAROV Pulley System, with the exception of the newly modified struts added to the construct. The subject Circular Fixation with Balanced Cable Transport will consist of wires, cables, pulleys, and struts, in comparison to the predicate ILIZAROV Pulley System, consisting of rings, threaded rods, bolts, nuts, washers, pin clamps, wire fixation, pins, wires, cables and pulleys.

Substantial Equivalence Information

The overall materials, intended use, indications for use, and the modified subject device design for the Circular Fixation with Balanced Cable Transport, are substantially equivalent to the following commercially available predicate device.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	ILIZAROV Pulley System	K042436	10/07/2004

510(k) SUMMARY

Performance Testing

To further support a determination of substantial equivalence, non-clinical bench testing was conducted on the subject Circular Fixation with Balanced Cable Transport. A review of the testing indicates that the subject Circular Fixation with Balanced Cable Transport is substantially equivalent to predicate device listed in the **Table 6.1** above.

The following tests were used as a basis for the determination of substantial equivalence. The substantial equivalence of the subject devices can be found in Section 13. Provided below is a brief summary of the results that these tests yielded.

- Bone Transport Testing
  - Based on this analysis, there is no significant difference in the maximum load carrying capacity observed in the predicate device when compared to the subject devices.

- Biocompatibility
  - The subject struts of the Circular Fixation with Balanced Cable Transport, are equivalent to the previously marketed predicate device the ILIZAROV Pulley System (K042436) in formulation, processing, and sterilization, with the modified subject devices (struts), classified as Class II non-sterile, non-patient contacting instrument devices, that defaults to a low risk categorization and the ISO 10993-1 not applicable.

510(k) SUMMARY

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the subject Circular Fixation with Balanced Cable Transport. Based on the similarities to the predicate device, ILIZAROV Pulley System, and a review of the Bone Transport Testing, we believe the subject devices are substantially equivalent to the commercially available predicate device listed above.