January 19, 2021

Sequel Medical Inc.
Valentina Kamysheva
CEO
12550 Biscayne Blvd Ste 110
North Miami, Florida 33181-2536

Re: K202833
Trade/Device Name: Sequel External Fixation Device
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 23, 2020
Received: November 20, 2020

Dear Valentina Kamysheva:

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)*
K202833

Device Name

Sequel External Fixation Device

Indications for Use *(Describe)*

The Sequel Ring Fixation System is indicated for both adults and pediatric patients for:

1. Open and closed fracture fixation
2. Pseudoarthrosis or non-union of long bones
3. Limb lengthening by epiphyseal or metaphyseal distraction
4. Correction of bony or soft tissue deformities
5. Correction of segmental or nonsegmental bony or soft tissue defects
6. Post-Traumatic joint contracture which has resulted in loss of range of motion

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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K202833 - 510(K) SUMMARY

In accordance with 21 CFR 807.92 the following information is provided for the Sequel External Fixation System 5110(k) premarket notification.

1. SUBMITTER

Applicant: Sequel Medical
12550 Biscayne Blvd.
Suite 110
Miami, Fl 33181

Contact Person: Valentina Kamysheva
CEO
Sequel Medical
12550 Biscayne Blvd.
Suite 110
Miami, Fl 33181
Phone: 1-305-814-8299
Email: Valentina@sequelmd.com

Date Prepared: August 19, 2020

2. DEVICE

Name of Device: Sequel External Fixation System

Common or Usual Name: Multilateral Fixator Components

Regulatory Class: II

Product Code: KTT- Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

FDA Panel: Division of Orthopedic Devices

3. PREDICATE DEVICES

Predicate Device:

K190486
Pitkar External Fixation System
S H Pitkar Orthotools Pvt Ltd.
Plot No. EL 32, J Block, MIDC Bhosari
Pune, IN 411026

Secondary Predicate Devices:

K071394
SBi RingFIX™ System
Small Bone Innovations Inc.
505 Park Ave., 14th Floor
New York, NY 10022

K170650
Orthofix TrueLok Hexapod System (TL-HEX) V2.0
Orthofix Srl
Via Delle Nazioni 9
Bussolengo, IT 37012

4. GENERAL DESCRIPTION

The Sequel® External Fixation System is a single-use modular external fixator consisting of implantable half pins and fixation wires and non-patient contact rings, 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. The Subject device includes additional components (tabbed rings and struts) compared to the primary predicate. The tabbed rings and struts are substantially equivalent to the tabbed rings and struts in the secondary predicates. Special wrenches and accessories are included for the proper assembly of the components. The components of the frame are manufactured from titanium, stainless steel, and aluminum.

5. INDICATION FOR USE STATEMENT

The Sequel® External Fixation System is indicated for both adult and pediatric patients for:

1. Open and closed fracture fixation
2. Pseudoarthrosis or non-union of long bones
3. Limb lengthening by epiphyseal or metaphyseal distraction
4. Correction of bony or soft tissue deformities
5. Correction of segmental or nonsegmental bony or soft tissue defects
6. Post-Traumatic joint contracture which has resulted in loss of range of motion

6. SUBSTANTIAL EQUIVALENCE

Comparison of Intended Use:

The intended use of the Sequel® External Fixation System is equivalent to the intended use for the primary predicate. The system is intended used to provide stabilization of open and/or closed unstable fractures and other indicated corrective procedures.

Indications for Use:

The indications for use of the Sequel® External Fixation System are equivalent to the indications for use cleared for the primary predicate. Like the primary predicate, the Sequel® External Fixation System indicated for both adult and pediatric patients for open and closed fracture fixation, pseudoarthrosis or non-union of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, correction of segmental or nonsegmental bony or soft tissue defects, and post-traumatic joint contracture which has resulted in loss of range of motion.

Technology Comparisons:

Table 1 below compares the key technological feature of the subject devices to the predicate devices.

Table 1: Technological Comparison

	Subject Device	Primary Predicate	Secondary Predicate	Secondary Predicate
510(k) Number	**K202833**	**K190486**	**K071394**	**K170650**
Device Name	**Sequel® External Fixation System**	**Pitkar External Fixation System**	**SBi RingFIXTM System**	**Orthofix TrueLok Hexapod System (TL-HEX) V2.0**
Classification Regulation	**Class II**	**Class II**	**Class II**	**Class II**
Classification Product Code	**KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component**	**KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component**	**KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component**	**KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component**
Subsequent Product Code	**Not Applicable**	**JDW - Pin, Fixation, Threaded**	**Not Applicable**	**OSN: Software for Diagnosis/Treatment**
Operating Principle	**Ilizarov Apparatus Method - Distraction - Osteogenesis**	**Ilizarov Apparatus Method - Distraction Osteogenesis**	**Ilizarov Apparatus Method - Distraction Osteogenesis**	**Ilizarov Apparatus Method - Distraction Osteogenesis**
Components	**External Fixator Frame Components.** **Tabbed rings** **Tabbed Struts**	**External fixator components.** **NA** **NA**	**External fixator components.** **Tabbed rings** **NA**	**External fixator components.** **NA** **Tabbed Struts** **May be used with a web-based software component that is designed to be used to assist the physician in creating a patient adjustment schedule that assists in adjusting the six struts**
Materials of Construction	**Titanium Stainless Steel Aluminum**	**Titanium Stainless Steel Aluminum**	**Aluminum**	**Aluminum**
Sterilization	**Supplied non-sterile in a sterilization tray to be sterilized by moist heat (autoclave) prior to use.**	**Supplied non-sterile in a sterilization tray to be sterilized by moist heat (autoclave) prior to use.**	**Supplied non-sterile in a sterilization tray to be sterilized by moist heat (autoclave) prior to use.**	**Supplied non-sterile in a sterilization tray to be sterilized by moist heat (autoclave) prior to use.**

7. PERFORMANCE TESTING

Biocompatibility Testing:

The components of the Sequel® External Fixation System frame are not in direct contact with patient tissue. The frame components are not within the scope of ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. The frame components are manufactured from the same material, by an equivalent manufacturing process, and to the same dimensional specifications as the primary predicate. The tabbed rings and struts are manufactured from the same material, by an equivalent manufacturing process and to the same dimensional specifications as secondary predicates. Therefore, biocompatibility testing is not required to prove substantial equivalence of the subject device. Refer to Table 2.

The implantable half pins and fixation wires are manufactured from 316L stainless steel a material routinely used in implantable medical devices. The components are made by an equivalent manufacturing process and to the same dimensional specifications as the predicate devices. Therefore, biocompatibility testing is not required to prove substantial equivalence of the subject device. Refer to Table 2.

Table 2 – Biocompatibility Evaluation Subject Device vs Predicates

	Patient Contact	Material of Construction	Manufacturing Process	Dimensional Specifications	Sterilization Method
Frame Components	Same No Direct Patient Contact	Same	Equivalent	Same	Same (Moist Heat)
Tabbed Rings and Tabbed Struts	Same No Direct Patient Contact	Same	Equivalent	Same	Same (Moist Heat)
Half Pins	Same Implantable	Same	Equivalent	Same	Same (Moist Heat)
Fixation Wires	Same Implantable	Same	Equivalent	Same	Same (Moist Heat)

Bench Testing

Bench testing for the characterization of the design and mechanical function of Sequel® External Fixation System was performed in accordance with ASTM F1541-17 Standard Specification and Test Methods for External Skeletal Fixation. The Sequel® External Fixation System conformed to the requirements and specification of this standard.

Sterilization Validation

The Sequel® External Fixation System is provided non-sterile in a sterilization tray. The Instructions for Use Manual specifies moist heat (autoclave) sterilization cycle parameters for the health care institution to sterilize the device prior to use. The recommended sterilization cycle was validated in accordance with ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices and ISO/TS 17665-2:2009 Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

The substantial equivalence information provided in this submission demonstrates that the subject device is substantially equivalent to the predicate devices in both indications for use and technological characteristics. The additional components compared to the primary predicate are substantially equivalent to the components in the secondary predicates. The addition of the new components does not raise new questions of safety or effectiveness. The performance test results demonstrate that the device continues to meet all the specifications and requirements that were met by the predicate devices. Therefore, the subject device can be found substantially equivalent to the predicate devices