March 19, 2018

Anjon Holdings, LLC
% Mr. John Kapitan
Chief Executive Officer
Kapstone Medical
P.O. Box 969
Leicester, North Carolina 28748

Re: K171863
Trade/Device Name: Anjon Bremer Halo System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JEC
Dated: March 9, 2018
Received: March 12, 2018

Dear Mr. Kapitan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K171863

Device Name
Anjon Bremer Halo System

Indications for Use *(Describe)*
The Anjon Bremer Halo System is indicated for use to provide cervical spine immobilization and therapeutic traction for treatment of patients with cervical trauma or other neck condition.

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

1. Applicant

Anjon Holdings, LLC
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Jacksonville, FL 32207

2. Official Correspondent

Kapstone Medical, LLC
PO Box 969
Leicester, NC 28748

Contact Person:
John Kapitan, CEO
Tel: (704) 843-7852
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3. Date Prepared:

19 June 2017

4. Device Name

Trade: Anjon Bremer Halo System
Common/Usual Name: External fixator system
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 888.3040
Product Code: JEC
Classification: II
Panel: Orthopedic

5. Predicate Devices

The Anjon Bremer Halo System is substantially equivalent to the Bremer Halo System Cervical Traction Skull Pin produced by Bremer Medical, Inc and the Bremer Halo System Titanium Skull Pin produced by DePuy Acromed, marketed as Bremer Halo System. The Bremer Halo System Cervical Traction Skull Pin is the Primary Predicate and the Bremer Halo System Titanium Skull Pin is a Reference Predicate, as shown below with corresponding 510(k) numbers.

Predicate	510(k) Number	Device	Manufacturer
Primary	K915800	Bremer Halo System Cervical Traction Skull Pin	Bremer Medical, Inc
Reference	K993099	Bremer Halo System Titanium Skull Pin	De Puy Acromed

Table 1-1: Predicate devices

6. Description of the Device

The Anjon Bremer Halo System consists of transcutaneous bone anchorage elements, and extracutaneous bridge elements, which provide fixation of the skull relative to the torso to immobilize the cervical spine when used with a frame or surgical table adaptor.

The transcutaneous bone anchorage elements are titanium threaded skull pins, of which four (4) skull pins attach to an aluminum crown or ring positioned below the head equator. The crown or ring is then attached to an aluminum rod superstructure, which is attached to a lined polymer vest, or attached to a surgical table using the Mayfield adaptor. All materials are MRI/CT conditional.

Fixation of the selected bridge element (crown or ring) to the patient skull is accomplished using tight connection of the titanium threaded skull pins up to a maximum specified torque. The head is then held in extension when the frame (vest and superstructure) are connected to the bridge element, at which time reduction occurs. For rigid support during diagnostic examination or surgical procedure, the bridge element can be connected to the surgical table through use of the Mayfield adaptor. Cervical spine immobilization and therapeutic traction occurs as localized rotation and flexion motion is eliminated.

7. Indications for Use

The Anjon Bremer Halo System is indicated for use to provide cervical spine immobilization and therapeutic traction for treatment of patients with cervical trauma or other neck condition.

8. Summary of Technological Characteristic Comparison

The technological characteristics of the Anjon Bremer Halo System are equivalent to the predicate devices, as outlined in Table 1-2 below.

Applicant	Anjon LLC	Bremer Medical, Inc	De Puy Acromed
	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
Product Name	Anjon Bremer Halo System	Bremer Halo System Cervical Traction Skull Pin	Bremer Halo System Titanium Skull Pin
510(k) Number	TBD	K915800	K993099
Product Code	JEC	JEC	JEC, HWC
Regulation #	21CFR 888.3040	21CFR 888.3040	21CFR 888.3040
Class	II	II	II
Prescription or O-T-C?	Prescription	Prescription	Prescription
Provided Sterile or Non-sterile?	Non-sterile	Sterile	Sterile
Indications for Use	Intended for use to provide cervical spine immobilization and therapeutic traction for treatment of patients with cervical trauma or other neck condition	Intended for use to provide cervical spine immobilization and therapeutic traction for treatment of patients with cervical trauma or other neck condition	Intended for use in conjunction with Bremer's Halo System cervical traction devices and accessories, which provide cervical immobilization for treatment of patients for healing and rehabilitation of cervical spinal cord injuries
Components	Crown (Metal) Adjustable Ring (Metal) Positioning Pins (Polymer) Positioning Pads (Polymer) Plastic molded vest (Polymer) Vest liner (synthetic lambskin) Rod superstructure (metal) with halo clamps (polymer) Threaded screw skull pin (Alloy) Torque Limiter (Polymer)	Halo Crown (Metal) Adjustable Halo Ring (Metal) Positioning Pins (Polymer) Positioning Pads (Polymer) Plastic molded vest (Polymer) Vest liner (synthetic lambskin) Rod superstructure (metal) with halo clamps (polymer) Threaded screw skull pin (Alloy) Torque Limiter (Polymer)	Threaded screw skull pin (Alloy)

Applicant	Anjon LLC	Bremer Medical, Inc	De Puy Acromed
	SUBJECT DEVICE	**PRIMARY PREDICATE**	**REFERENCE PREDICATE**
Product Name	**Anjon Bremer Halo System**	**Bremer Halo System Cervical Traction Skull Pin**	**Bremer Halo System Titanium Skull Pin**
Accessories	Torque wrench Head spoon ICU Fast Release Bolts Mayfield Adapter Set	Torque wrench Head spoon ICU Fast Release Bolts Mayfield Adapter Set	Not applicable
Sterilization Methodology	Not applicable	Ethylene Oxide	Ethylene Oxide
MRI Safety	MR Conditional	MRI Compatible	MRI Compatible

Table 1-2: Overview of Substantial Equivalence

9. Conclusion

The Anjon Bremer Halo System is substantially equivalent to the Bremer Halo System Cervical Traction Skull Pin predicate device (Primary Predicate - K915800) and Bremer Halo System Titanium Skull Pin (Reference predicate - K993099). In addition to conclusions from performance data comparisons, the devices have the same "Indications for Use," and are available by prescription only, and are for single use only. The devices utilize 356-T-6 aluminum, Wrought Titanium-6Aluminum-4Vanadium ELI, Aluminum 6061-T6, Nylon 66 resin containing 50% Long Glass, and Resinol type A (LPDE). It can be concluded that the Anjon Bremer Halo System is substantially equivalent to the predicate device.