March 2, 2020

Anjon Holdings LLC
Kenneth Collins
General Manager
4801 Dawin Road
JACKSONVILLE, FL 32207

Re: K193256
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: February 7, 2020
Received: February 10, 2020

Dear Kenneth Collins:

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
Acting 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)*

K193256

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

Applicant

Anjon Holdings, LLC
4801 Dawin Rd
Jacksonville, FL 32207

Official Correspondent/Contact Person

Kenneth A Collins
General Manager
Anjon Holdings LLC

Tel: (904) 730-9373
Email: kcollins@anjonholdings.com

Date Prepared: 25 February , 2019

Device Name

Trade name:	Anjon Bremer Halo System
Common/Usual Name:	Cervical external halo fixature
Classification Name:	Component, traction, invasive
Regulation Number:	888.3040
Product Code:	JEC
Classification:	II
Panel:	Orthopedic

Predicate Devices

The Anjon Bremer Halo System acts as its own predicate. In addition 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.

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Table 2 Predicate devices

510(k) Number	Device	Manufacturer
K171863	Anjon Bremer Halo System	Anjon LLC
K915800	Bremer Halo System Cervical Traction Skull	Bremer Medical, Inc
K993099	Bremer Halo System Titanium Skull Pin	De Puy Acromed

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.

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.

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.

Summary of Technological Characteristic Comparison

The technological characteristics of the Anjon Bremer Halo System are equivalent to the predicate devices, as outlined in Table 3 below.

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Table 3 Comparison to Predicate

Applicant	Anjon LLC	Anjon LLC	Bremer Medical, Inc	De Puy Acromed
	SUBJECT DEVICE	Primary Predicate	PREDICATE	PREDICATE
Product Name	Anjon Bremer Halo System	Anjon Bremer Halo System	Bremer Halo System Cervical Traction Skull Pin	Bremer Halo System Titanium Skull Pin
510(k) Number	TBD	K171863	K915800	K993099
Product Code	JEC	JEC	JEC	JEC, HWC
Regulation #	21CFR 888.3040	21CFR 888.3040	21CFR 888.3040	21CFR 888.3040
Class	II	II	II	II
Prescription or O-T-C?	Prescription	Prescription	Prescription	Prescription
Provided Sterile or Non-sterile?	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 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 or Nylon 66/Glass 50%)**	**Crown (Metal) Adjustable Ring (Metal) Positioning Pins (Polymer)**	**Halo Crown (Metal) Adjustable Halo Ring (Metal) Positioning Pins (Polymer)**	**Nylon 66/Glass 50% chopped strand co-extrusion.**

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Applicant	Anjon LLC	Anjon LLC	Bremer Medical, Inc	De Puy Acromed
	SUBJECT DEVICE	Primary Predicate	PREDICATE	PREDICATE
Product Name	Anjon Bremer Halo System	Anjon Bremer Halo System	Bremer Halo System Cervical Traction Skull Pin	Bremer Halo System Titanium Skull Pin
	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) – spi9ke or drill tip. Torque Limiter (Titanium)	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)	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) – drill tip
Accessories	Torque wrench Head spoon ICU Fast Release Bolts Mayfield Adapter Set	Torque wrench Head spoon ICU Fast Release Bolts Mayfield Adapter Set	Torque wrench Head spoon ICU Fast Release Bolts Mayfield Adapter Set	Not applicable

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Applicant	Anjon LLC	Anjon LLC	Bremer Medical, Inc	De Puy Acromed
	SUBJECT DEVICE	Primary Predicate	PREDICATE	PREDICATE
Product Name	Anjon Bremer Halo System	Anjon Bremer Halo System	Bremer Halo System Cervical Traction Skull Pin	Bremer Halo System Titanium Skull Pin
Sterilization Methodology	Co_{60} Gamma Irradiation	Not applicable	Ethylene Oxide	Ethylene Oxide

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Description of Non-Clinical Testing

Non-clinical testing of the Anjon Bremer Halo System in support of this submission included the following activities:

- Testing of the Skull Pins to failure under load (ASTM F1541).
- Biocompatibility assessment of the manufactured Skull Pins which included elution-based Cytotoxicity, Sensitization, Intracutaneous Reactivity and Material Mediated Pyrogenicity testing (ISO 10993).
- Testing of the Halo for deformation under load at maximal load and sustained half load conditions (ASTM F1831).
- Testing of the product and sterile barrier per ISO 11607-2:
    - Product stability after high dose gamma irradiation and accelerated aging after simulated one- and three-year aging. This included repeating at each time point:
        - Testing of the Skull Pins to failure under load (ASTM F1541).
        - Testing of the Halo for deformation under load at maximal load and sustained half load conditions (ASTM F1831).
    - Sterile barrier stability and integrity tests after simulated transportation stress.
    - Sterile barrier stability and integrity tests after high dose gamma irradiation and accelerated aging at simulated one- and three-year aging.

The above testing was done in addition to the studies required to validate the sterility of the product using the VDmax25 method (ISO 11137).

Conclusion

As documented in this submission, the gamma sterilized Anjon Bremer Halo System is substantially equivalent to its own Anjon Holdings' predicate cleared per K171863.
In addition, as a product range extension:

- The polymer Molded Crown variant of the Halo Crown is substantially equivalent to the anodized aluminium variant cleared per K171863.
- The drill tip Traction Skull Pin (PIN010) is substantially equivalent to the skull pins initially cleared under K171863, the Bremer Halo System Cervical Traction Skull Pin predicate device (Primary Predicate - K915800) and Bremer Halo System Titanium Skull Pin (Reference predicate - K993099).

The devices are available by prescription only, and are for single use only. The devices utilize 356-T-6 aluminum, Wrought Titanium-6Aluminum-4VanadiumELI, Aluminum 6061-T6, Nylon 66 resin containing 50% Long Glass, and Resinol type A(LDPE).

It can be concluded that the Anjon Bremer Halo System is substantially equivalent to the predicate devices.