Baat Medical Products BV
Teake Bulstra
Product Manager
F. Hazemeijerstraat 800 - Building A04
RJ Hengelo, 7555
Netherlands

August 27, 2020

Re: K201830
Trade/Device Name: ANSER Clavicle Pin
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDW
Dated: July 2, 2020
Received: July 2, 2020

Dear Teake Bulstra:

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,

For Michael Owens, MS, RAC
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)*
K201830

Device Name
ANSER Clavicle Pin

Indications for Use *(Describe)*
The ANSER Clavicle Pin is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. Traditional 510(k) Summary

1. Date of preparation:

August 27, 2020

2. Applicant:

BAAT Medical
F. Hazemeijerstraat 800
7555 RJ Hengelo
Phone: +31 (0)88-5656600
Contact person: Teake Bulstra
Email: Teake@baatmedical.com

The summary contains on the first page, preferably on your letterhead paper, the 510(k) owner's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)].

3. Device Information

510(k) Number:	K201830
Trade Name:	ANSER Clavicle Pin
Classification name:	Intramedullary fixation rod
Regulation number:	21 CFR §888.3020
Regulation Description:	An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures
Regulatory Class:	II
Product Code:	HSB
Panel:	Orthopedic

4. Indications for Use

The ANSER Clavicle Pin is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

5. Description of the Device

The ANSER Clavicle Pin is a device intended to be used for intramedullary fixation of mid-shaft clavicle fractures. The device consists of three parts. The main component is a nail, that is placed within the medullary canal of the fractured clavicle. It has a threaded medial end for fixation into the bone. At the lateral end an endcap is placed after insertion for lateral fixation of the pin. In this way the pin is secured both medially and laterally.

6. Predicate Device(s)

The ANSER Clavicle Pin is substantially equivalent to the following devices:

Primary Predicate: K182783	DePuySynthes - Elastic Intramedullary Nail (EIN; also known as Titanium Elastic Nail or TEN) (primary predicate)
Reference Device: K163488	Intrafuse LLC - Flex-Thread Clavicle Pin System (additional predicate)

7. Technological Characteristics Comparison:

The ANSER Clavicle Pin and the Flex-Thread Clavicle Pin System are similar in design, function and size. Each device is designed to fix fractures from within the intramedullary canal. The subject and predicate device designs possess the ability to engage curved regions of the intramedullary canal. All three devices (ANSER Clavicle Pin, Elastic Intramedullary Nail, Flex-Thread Clavicle Pin) have flexibility and can be curved to fit the anatomy. All three devices can be secured in the lateral cortex of the clavicle.

The ANSER Clavicle Pin and the Elastic Intramedullary Nail are manufactured from Ti alloy. The Flex-Thread System contains stainless steel and polyetheretherketone (PEEK). All these materials have been used in fracture fixation systems of the clavicle without issue and have well-established biocompatibility and a long history of use in many previously cleared permanent implants.

Mechanical testing demonstrates that the design differences between the ANSER Clavicle Pin, Flex-Thread Clavicle Pin and the Elastic Intramedullary Nail introduce no new issues of safety or effectiveness.

The ANSER Clavicle Pin has a length of 180 mm and a diameter of 2.2 mm. The EIN has a length of 440 mm and a diameter of 1.5 - 4.0 mm. The size range of the EIN is larger because it is indicated for fractures in a range of upper and lower extremity long bones. The products with a diameter of 1.5 - 2.5 mm are indicated for use in the clavicle bone. The diameter of the ANSER Clavicle Pin is within this range.

8. Summary of Performance Data

The ANSER Clavicle Pin has been subject to mechanical performance testing, including:

- ASTM F1264 Static & Fatigue 4-Point Bending Testing
- ASTM F1264 Static Torsion Testing
- ASTM F543 Insertion & Removal Testing

Results demonstrate equivalent mechanical performance as the predicate devices. No clinical data is presented.

9. Substantial Equivalence Conclusion

The ANSER Clavicle Pin is demonstrated to be substantially equivalent to the primary and additional predicate devices cited above, in terms of intended use, material, design, mechanical properties and function.