October 22, 2026

BAAT Medical Products B.V.
Jasper Springer
Regulatory Affairs Officer
F. Hazemeijerstraat 800
Bldg. A04
Hengelo, 7555RJ
Netherlands

Re: K262184
Trade/Device Name: GANNET®
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDO, HSB, KTT
Dated: September 23, 2026
Received: September 23, 2026

Dear Jasper Springer:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

LIMIN SUN -S

Limin Sun, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262184

Please provide the device trade name(s).

GANNET®

Please provide your Indications for Use below.

The GANNET® implant is intended for use in fracture fixation in the proximal femur in adults.

The GANNET® implant is indicated for use in:
- Intracapsular and extracapsular fractures of the femoral neck
- Trochanteric fractures of the proximal femur
- Stable subtrochanteric fractures of the proximal femur

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary

1. Applicant/Submitter

Submitter Name:	BAAT Medical Products B.V.
Submitter Address:	F. Hazemeijerstraat 800 - Building A04 7555 RJ Hengelo The Netherlands
Phone Number:	+31-(0)88-5656600
Contact person:	Jasper Springer
Date Prepared:	22th of October 2026

2. Device

Device Trade name:	GANNET®
Common Name:	Device, Fixation, Proximal Femoral, Implant
Classification Name and Regulation Number:	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Classification:	II
Product Code/s:	JDO (primary), HSB, KTT
Review Panel:	Office of Orthopedic Devices (OHT6)

3. Predicate Device

Primary Predicate:

X-BOLT® Dynamic Hip Plating System (K181640)

Additional Predicates:

Dynamic Hip System DHS Screw (K791619)
Omega™ 3 system Hansson™ Twin Hook (K062066)

4. Description of the Device

The GANNET® implant is a device for surgical fixation of femoral neck, trochanteric fractures and stable subtrochanteric fractures. The system is comprised of three main components: a blade for stable fixation within the femoral head, a barreled side-plate that facilitates controlled sliding and dynamization, and cortical bone screws for secure attachment to the femur:

- GANNET® Blade;
- GANNET® Plate;
- GANNET® Screws.

Together, these components are used for the extramedullary fracture stabilization, supporting both mechanical stability and bone healing. The implants are delivered sterile to the end-user. The implants are meant for single use. The GANNET® is implanted with dedicated instruments.

5. Indication for Use Statement

The GANNET® implant is intended for use in fracture fixation in the proximal femur in adults.

The GANNET® implant is indicated for use in:

- Intracapsular and extracapsular fractures of the femoral neck;
- Trochanteric fractures of the proximal femur;
- Stable subtrochanteric fractures of the proximal femur.

6. Summary of Technological Characteristics of the Device Compared to the Predicate device

The GANNET® implant and the predicate share a common overall design architecture consisting of a proximal fixation element, a barreled side-plate, and cortical bone screws. Both devices are intended to stabilize proximal femoral fractures through engagement within the femoral head and neck combined with fixation to the femoral shaft.

The devices differ in the mechanism used to achieve fixation within the femoral head. The GANNET® utilizes two expanding anchors, whereas the predicate device utilizes four expanding wing elements. Despite this technological difference, both devices employ expandable fixation elements within the femoral head and operate according to the same fundamental principle of fracture fixation. The differences do not raise different questions of safety and effectiveness. Similar fixation concepts are present in other legally marketed devices within this device family, supporting that the technological differences do not introduce new questions of safety and effectiveness.

7. Summary of Performance Data, Clinical Data, and Design Controls

The GANNET® has undergone non-clinical performance testing to evaluate mechanical integrity and functional performance relative to the predicate device and, where applicable, reference devices.

Testing was conducted in accordance with FDA-recognized consensus standards, including ISO 14630, ASTM F384, ASTM F543 and ASTM F1839. The testing included evaluation of static and dynamic compression testing, cut-out testing, rotation testing, pullout testing, anchor expansion testing, anchor deployment, torsional strength testing, driving torque testing and hammer testing.

Biocompatibility was addressed in accordance with ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. A risk-based biological evaluation was performed considering the materials, manufacturing processes, and clinical use of the device. Based on this evaluation and supporting evidence, the device is considered biocompatible and safe for its intended use.

The results of the non-clinical performance testing demonstrate that the GANNET® meets its predetermined performance specifications and is suitable for its intended use. The results support the conclusion that the GANNET® performs at least as safely and effectively as standard hip fixation devices under similar conditions of use.

8. Conclusion of Substantial Equivalence

The GANNET® has the same intended use, similar indications for use, similar technological characteristics, similar principles of operation, same range of size parameters, and similar materials as the identified predicate device.

The differences encountered do not negatively impact the overall safety and effectiveness of the GANNET®. Therefore, it can be concluded that the GANNET® is a safe and effective device and is substantially equivalent to the identified predicate system.