June 5, 2024

aap Implantate AG
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K233008
Trade/Device Name: Cannulated Headless Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 14, 2024
Received: May 14, 2024

Dear Kevin Thomas:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233008

Device Name

Cannulated Headless Bone Screws

Indications for Use *(Describe)*

Cannulated Headless Bone Screws
The aap Cannulated Headless Bone Screws are indicated for use in non-spinal fracture and fragment fixation, osteotomy and arthrodesis of human bones appropriate for the size of the screw. The devices are intended for single use only.
The aap Cannulated Headless Bone Screws are indicated for adults, and children (2 years to less than 12 years) and adolescents (aged 12 through 21, up to but not including the 22nd birthday) in which growth plates have fused or in which growth plates will not be crossed by fixation.

K-Wire
K-Wires are indicated for use as guide wire for osteosynthesis implants and for application as implant according to the AO/ASIF principles of fracture management.
The K-Wires are indicated for adults, and children (2 years to less than 12 years) and adolescents (aged 12 through 21, up to but not including the 22nd birthday) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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.

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510(k) Summary
K233008
Cannulated Headless Bone Screws
aap Implantate AG

May 30, 2024

ADMINISTRATIVE INFORMATION

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Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Cannulated Headless Bone Screws
Common Name	Screw, fixation, bone
Regulation Number	21 CFR 888.3040
Regulation Name	Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Primary Product Code	HWC
Additional Product Codes	HTY
Classification Panel	Orthopedic
Reviewing Office	Office of Health Technology 6 (OHT 6: Orthopedic Devices)
Reviewing Division	Division of Health Technology 6 C (Restorative, Repair and Trauma Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K111316, aap Cannulated Screws, aap Implantate AG

Reference Devices
K130590, aap Cannulated Screw 2.0, aap Implantate AG
K131459, aap Wire Bone, aap Implantate AG
K161616, DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws, DePuy Synthes 2.4 mm Cannulated Screws, DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws, DePuy Synthes 4.5 mm Cannulated Screws, DePuy Synthes 6.5 mm Cannulated Screws, DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws, DePuy Synthes 1.5 mm Headless, Synthes USA Products, LLC

INDICATIONS FOR USE STATEMENT

Cannulated Headless Bone Screws

The aap cannulated headless bone screws are indicated for use in non-spinal fracture and fragment fixation, osteotomy and arthrodesis of human bones appropriate for the size of the screw. The devices are intended for single use only. The aap Cannulated Headless Bone Screws are indicated for adults, and children (2 years to less than 12 years) and adolescents (aged 12 through 21, up to but not including the 22nd birthday) in which growth plates have fused or in which growth plates will not be crossed by fixation.

K-Wire

K-Wires are indicated for use as guide wire for osteosynthesis implants and for application as implant according to the AO/ASIF principles of fracture management.

The K-Wires are indicated for adults, and children (2 years to less than 12 years) and adolescents (aged 12 through 21, up to but not including the 22nd birthday) in which growth plates have fused or in which growth plates will not be crossed by fixation.

SUBJECT DEVICE DESCRIPTION

The subject device Cannulated Headless Bone Screws are cannulated and threaded at both the leading end (tip) and at the trailing end. The leading/trailing diameters are: 2.5/3.4 mm, 3.0/3.8 mm, 3.5/4.5 mm, 4.0/4.8 mm, 4.5/5.3 mm, 5.5/6.2 mm, 6.5/7.2 mm, and 7.5/7.9 mm., The leading thread and the trailing thread have different pitches which facilitates closure of any fracture gap and generates compression across the bone fragments. The subject screws are provided in overall lengths ranging from 12 mm to 140 mm, and with threaded lengths (at the leading end or tip) ranging from 4 mm to 40 mm. The subject screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3.

The subject K-Wire is provided in one size with a diameter of 2.4 mm and a length of 250 mm. The subject K-Wire has a trocar point, is threaded, and is manufactured from stainless steel conforming to ASTM F138 and ISO 5832-1.

PERFORMANCE DATA

Recognized standards used in the non-clinical performance testing included:

ASTM F136 (2013) *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*;

ISO 5832-3 (2021) *Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*;

ASTM F138 (2019) *Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)*;

ISO 5832-1 (2016) *Implants for surgery – Metallic materials – Part 1: Wrought stainless steel*;

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*;

ISO 17665-2 (2009) *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*;

ISO 10993-1 (2018) *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*; and

ASTM F543 (2017) *Standard Specification and Test Methods for Metallic Medical Bone Screws*.

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- referenced from for the primary predicate K111316 and the reference devices K130590 and K131459 was moist heat sterilization validation to a sterility assurance level of 10^{-6} by the overkill method according to

ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO TIR 17665-2, and ANSI/AAMI/ISO 14937; analysis showed that the subject devices do not create a new worst case for moist heat sterilization;

- referenced from K111316, K130590, and K131459 was packaging and shelf life information for the subject devices;
- referenced from K111316, K130590, K131459 was biocompatibility for the subject device materials;
- provided in this submission was mechanical testing of the subject device screws according to ASTM F543.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device, the primary predicate device K111316, and the reference devices K130590 and K131459 have the same technological characteristics and use the same operating principles for bone fracture fixation (bone screws and K-Wire) or for use as an instrument (K-Wire to facilitate placement of cannulated screws). The reference device K161616 is to support the use of the subject screws in the pediatric population.

The subject device bone screws are provided in ranges of thread diameters, threaded lengths, and overall lengths that are similar to the primary predicate K111316 and the reference device K130590. The subject screw designs also are similar to the designs of screws cleared in K111316 and K130590.

The subject device K-Wire has a diameter of 2.4 mm, an overall length of 250 mm, and a trocar point. These dimensions are within the range of K-Wires (with trocar point) cleared in K131459.

The subject device screws are manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3 using materials and processes identical to that used for screws cleared in the primary predicate device K111316 and the reference device K130590.

The subject device K-Wire is manufactured from stainless steel confirming to ASTM F138 or ISO 5832-1 using processes identical to that used for K-Wires cleared in the reference device submission K131459.

All subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared aap device components. Therefore, the subject devices are substantially equivalent to predicate devices regarding biocompatibility.

The subject device components are provided non-sterile in the same packaging as in the primary predicate K111316 and the reference devices K130590 and K131459, and are to be sterilized to a sterility assurance level (SAL) of 10^{-6} by the end user using the same sterilization method (moist heat) and parameters as the previously cleared devices. The subject devices do not represent a new worst-case for the sterilization validation.

In support of substantial equivalence of the strength of the subject device screws mechanical testing was performed according to ASTM F543.

CONCLUSION

The subject devices, the primary predicate device, and the reference devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions, are manufactured from the same materials, and are to be sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.