October 7, 2025

metamorphosis GmbH
Dr. Stefanie Horstmann
Official Correspondent
Technologiepark 9
Paderborn, NRW 33100
Germany

Re: K252214
Trade/Device Name: AIAS Cephalon
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 15, 2025
Received: July 15, 2025

Dear Dr. Stefanie Horstmann:

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.

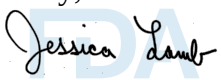
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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,



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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)*
K252214

Device Name
AIAS Cephalon

Indications for Use *(Describe)*
AIAS Cephalon is an image-processing software indicated to assist in the positioning of femur fracture implant components for adult patients. It is intended to assist in precisely positioning femur fracture implant components intraoperatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images (C-arm images). Clinical judgement and experience are required to properly use the device. The device is not for primary image interpretation. The software is not for use on mobile phones.

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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K252214

510(k) Summary

Submitter Information:

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Contact Person:

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Date Prepared: 09/11/2025

Device Name: AIAS Cephalon

Classification Name: Automated radiological image processing software

Regulation Number: 892.2050

Product Code QIH

Predicate Device: PhantomMSK Hip (K210136)

Device Description Summary:
AIAS Cephalon is a fully automated software as a medical device (SaMD) that provides image analysis features and intraoperative instructions for proximal femur fracture surgery supporting the positioning of the Depuy Synthes TFN-ADVANCED Proximal femoral nail (TFNA) implant.

The instructions are based on the intraoperative X-ray images acquired. The system automatically detects anatomy, implants, and tools in the X-ray images. Based on what it sees in the X-ray image, it provides different kinds of information. Every new X-ray image acquired triggers a new system response. This means updated information is only available when a new X-ray image is acquired.

AIAS Cephalon supports all of the following surgical steps of the procedure: determining the angle of anteversion and the Caput Collum Diaphyseal (CCD)/neck-shaft angle, finding the entry point at the greater trochanter, nail insertion, determination of length of head element, insertion of head element, distal locking of long TFNA nails, and determination of lengths of distal locking screws.

Intended Use/Indications for Use:
AIAS Cephalon is an image-processing software indicated to assist in the positioning of femur fracture implant components for adult patients. It is intended to assist in precisely positioning femur fracture implant components intraoperatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images (C-arm images). Clinical judgement and experience are required to properly use the device. The device is not for primary image interpretation. The software is not for use on mobile phones.

Indications for Use Comparison:
Both the predicate device and the subject device are intended to assist surgeons in precisely positioning implant components intraoperatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images (C-arm images).

Differences exist in the Indications for Use as the predicate is used for total hip replacement procedures and AIAS Cephalon is intended for femur fracture surgery. This aspect does not raise new or additional questions of safety and effectiveness as the main risks from the devices remain the same: A software error or use error could lead to a prolonged surgery and the need to re-take X-ray images.

Technological Comparison:
The subject device is a fully automated software, whereas the predicate device is semi-automated.
Extensive performance testing has demonstrated that the likelihood of unintended performance is adequately validated across the expected use cases.

Moreover, in the rare case of an incorrect detection, the user has the following two options:

i) the user may acquire a new fluoroscopic image, which will provide an updated detection of objects and anatomy, or
ii) the user may, at any time, proceed with the procedure conventionally at his/her own discretion without system guidance.

It is noted that both the predicate device and the subject device require clinical judgment and experience, and neither the predicate nor the subject device is intended for primary image interpretation.

Hence, given the extensive device validation, it can be concluded that the full automation does not raise different questions of safety and effectiveness.

Non-Clinical Tests Summary:
Software verification and validation was performed per metamorphosis's design and development process compliant with the IEC 62304:2015. Specifically, dedicated system verification testing including but not limited to automated tests, manual tests, and regression tests was performed against pre-defined acceptance criteria. Each test met its predefined acceptance criteria for all functions of the software.

Dedicated validation was performed on image processing accuracy. These evaluations were conducted using both comprehensive digitally reconstructed radiographic (DRR) datasets, which cover a wide range of real-world imaging scenarios, as well as real X-ray image data acquired from a study with human specimen. These evaluations have demonstrated that the acceptance criteria for the median error and 95% error quantiles of the measurements provided by the device (anteversion angle, CCD angle, head element length, tip-apex-distance, and distal locking screw length) are met.

The device uses several deep neural networks that contribute to determining the measurements of anteversion angle, CCD angle, head-element length, tip-apex-distance, and distal locking screw length. The performance of these deep neural networks was tested both stand-alone as well as integrated into the device. Each neural network was evaluated on at least 11,000 DRRs, which were computed from CT

scans of 18 patients of diverse demographic groups, covering a wide range of real-world imaging scenarios. The data set included 56% male and 44% female patients with an average age of 72.3 and 71.1 years, respectively, and the race/ethnicity distribution was 56% White, 28% Asian, 11% Hispanic or Latino, and 6% Black or African American. For all tests, the reference standard was validated by a senior orthopaedic surgeon. The patients whose CT scans were used to compute the DRRs for testing were not used for training the neural networks nor for tuning of any image processing algorithms. The evaluations have demonstrated that the acceptance criteria of the network-specific metrics of all neural networks are met. The neural networks used in this device are static and do not evolve over time, i.e., the models are fixed.

Human factors validation has been successfully performed to confirm that its user interface supports safe and effective use under realistic use conditions as well as to demonstrate that unintended performance of the fully automated imaging software across the variety of expected use cases is unlikely.

Substantial equivalence was not based on an assessment of clinical performance data.

Conclusion:
AIAS Cephalon has the same intended use as the predicate device. Differences in the indications for use, technological characteristics, and principles of operation compared to the predicate device do not raise different questions of safety or effectiveness. In addition, performance data demonstrates that the AIAS Cephalon does not raise different questions of safety or effectiveness. Thus, AIAS Cephalon is substantially equivalent to PhantomMSK Hip.