Corin USA Limited
Aaron Brunt
Senior Regulatory Affairs Specialist
12750 Citrus Park Lane
Tampa, FL 33625

January 7, 2025

Re: K241808
Trade/Device Name: ApolloHipX (THR.SS.0001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 21, 2024
Received: December 5, 2024

Dear Aaron Brunt:

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.

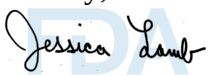
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier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



Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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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.

Submission Number *(if known)*

K241808

Device Name

ApolloHipX (THR.SS.0001)

Indications for Use *(Describe)*

ApolloHipX is indicated for use in assisting in Total Hip Replacement in which the use of radiological imaging may be appropriate.

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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510(k) #: K241808

510(k) Summary

Prepared on: 2025-01-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Corin USA Limited
Applicant Address	12750 Citrus Park Lane Tampa FL 33625 United States
Applicant Contact Telephone	+4407970237346
Applicant Contact	Mr. Aaron Brunt
Applicant Contact Email	aaron.brunt@coringroup.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ApolloHipX (THR.SS.0001)
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160284	JointPoint	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

ApolloHipX is a non-invasive intra-operative, image processing software intended to precisely measure the position of total hip replacement (THR) components. The software operates as a near-real time assistive device for THR, measuring component alignment, to assist in precise placement of THR components. The software is intended to be installed on certified hardware (Apollo Station) located outside the patient field. This is accomplished by:

- Transfer of intra-operative 2D imaging of the patient from a capture source e.g. an X-ray machine
- Registration of the 3D pre-operative patient data to the 2D intra-operative patient imaging
- Calculation and display of the component alignment (for final implants as well as intra-operative instruments e.g., broaches and trials) which can be compared to pre-operative target positions.

ApolloHipX is intended to precisely measure the position of THR components by measuring implant positions relative to bone structures identifiable from radiological images and providing information on component alignment.

Clinical judgment and experience of an orthopaedic surgeon are required to properly interpret the results from the software. The software is not for primary image interpretation.

The Apollo Station is the physical structure used to host the ApolloHipX system. It controls the power supply and contains two user interfaces (monitor and tablet) from which the user can interact with the software applications. It also houses non-surgical Software that manages the user authentication, system access, data transfer of surgical inputs and outputs, and communication to Corin's cloud-hosted ecosystem. The Apollo Station connects to the imaging device intra-operatively to receive the 2D radiological images.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ApolloHipX is indicated for use in assisting in Total Hip Replacement in which the use of radiological imaging may be appropriate.

Indications for Use Comparison 21 CFR 807.92(a)(5)

ApolloHipX is identical to JointPoint (K160284) in terms of intended use and indications for use intraoperatively. JointPoint is also intended for preoperative planning, ApolloHipX is not intended for preoperative planning. There are some slight differences in indications which do not alter the overall intended use or indications of the subject device nor do they impact the safety and effectiveness of the device relative to the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

ApolloHipX and JointPoint have identical measurement outputs related to cup position and orientation and measurements related to the stem and hip joint such as leg length (LL) and offset (OS). Both software products utilize a simulated templating feature, which allows users to view the simulated change in LL and OS measurements based on the current measured positions and selected components.

ApolloHipX differs from JointPoint in terms of preoperative templating and landmarking. Preoperative templating can be performed using JointPoint, however ApolloHipX does not have this feature. ApolloHipX accepts preoperative planning inputs, which are completed in OPSInsight (K202805) along with 3D bony model generation. ApolloHipX uses input of pre-operative patient landmarks identified from 3D CT, while JointPoint allows the user to define pre-operative patient landmarks identified from 2D radiographs.

Both systems utilise imaging to identify bone alignment and implant alignment between different patient states or positions. ApolloHipX uses 3D to 2D registration whilst JointPoint overlays 2D fluoroscopy images. Both softwares calculate and present measurements to the end user. Though both use different inputs, they both provide the same output.

Based on these similarities, Corin believes that ApolloHipX is considered to be substantially equivalent to the predicate device in terms of intended use and technological characteristics. Where differences exist between technological characteristics, they do not raise new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing conducted to determine substantial equivalence includes:
- Registration Software 2D Landmarking Repeatability and Reproducibility
- Registration System 3D Landmark Repeatability and Reproducibility
- Formative study
- Comparison Study of Fluoroscopy Imaging Types
- Algorithm Accuracy Study
- Sawbone study
- Cadaveric evaluation

Not Applicable. No clinical testing performed to support substantial equivalence.

The results of the tests conducted on the HipX system show that the device is substantially equivalent to the predicate devices. A comparison of intended use and indications for use also demonstrated substantial equivalence.