



May 29, 2026

OrthoGrid Systems, Inc.
Shweta Conner
Regulatory Affairs, Sr. Specialist
7026 S. Commerce Park Dr.
Suite 200
Midvale, Utah 84047

Re: K260077

Trade/Device Name: OrthoGrid Hip AI® 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 29, 2026
Received: April 29, 2026

Dear Shweta Conner:

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 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,



Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

K260077

?

Please provide the device trade name(s).

?

OrthoGrid Hip AI® 4.0

Please provide your Indications for Use below.

?

OrthoGrid Hip AI® 4.0 is an image-processing software indicated to assist in the positioning of Total Hip Replacement components. The software uses Artificial Intelligence (AI) to allow real-time initialization of grid placement relative to the bone structures of interest in C-arm fluoroscopic images to assist in precisely positioning Total Hip Replacement components intraoperatively by measuring their positions. Artificial Intelligence will only offer automated initialization of grid placement if the points of interest can be identified from radiology 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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OrthoGrid Hip AI® 4.0 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance documents, ‘The Special 510k Program Guidance for Industry and Food and Drug Administration Staff’, issued on September 13, 2019, ‘Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff’, issued on October 25, 2017, and ‘Deciding When to Submit a 510(k) for a Software Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff’, issued on October 25, 2017.

Sponsor: OrthoGrid Systems, Inc.
7026 South Commerce Park Drive
Suite 200
Midvale, UT, 84047
Establishment Registration Number: 9617840

Contact Person: Shweta Conner
Regulatory Affairs Sr, Specialist
Telephone: 901-569-3004

Date: May 29, 2026

Subject Device: **Trade Name:** OrthoGrid Hip AI® 4.0
Common Name: Automated Radiological Image Processing Software

Classification Name:
QIH– Medical Image Management And Processing System
(21 CFR §892.2050)

Predicate Device:

Manufacturer	Device Name	510(k) Number
OrthoGrid Systems, Inc.	PhantomMSK Hip	K210136

Device Description and Purpose:

The OrthoGrid Hip AI® 4.0 is a non-invasive Software as a Medical Device (SaMD) that uses non-generative Artificial Intelligence (AI) models to analyze fluoroscopic images to aid physicians with intra-operative implant and anatomic alignment and radiographic alignment for direct anterior total hip replacement procedures.

Alignment considerations during total hip replacement include pelvic tilt and obliquity, cup inclination and version, Leg Length and global offset. To assist users with these alignments, OrthoGrid Hip AI® 4.0 is an Artificial Intelligence-enabled product that provides digital annotations and visual guidance points on the fluoroscopic image using anatomic landmarks for functional pelvic plane tracking, cup positioning, leg length and offset. To operate OrthoGrid Hip AI® 4.0, a fluoroscopic image is acquired from a C-arm and displayed outside the sterile field, where the image analysis tools can be used at the user’s discretion.

OrthoGrid Hip AI® 4.0 operates on image principles that are compatible with both C-arm Image Intensifiers and Flat Panel C-arms. OrthoGrid Hip AI® 4.0 offers radiopaque Calibration Arrays in 9 and 12-inch sizes as an accessory for correction of fluoroscopic distortion for C-arm Image Intensifiers. Fluoroscopic distortion is attributed to external electromagnetic interference and the mapping of the planar image on a curved input phosphor.

OrthoGrid Hip AI® 4.0 does not include any custom computer hardware, and the software can be run on a “commercial off-the-shelf” system (i.e. PC, keyboard, mouse, touchscreen monitor etc.) that meets minimum performance requirements. As part of the System, all required computer accessories are provided to the customer.

The basis of this submission is the addition of optional non-generative artificial intelligence (AI) element for detection in fluoroscopic image of anatomic landmarks and objects to provide automated selection and initialization of measuring tools and pelvic position visual indicator. Addition of anatomical cup inclination and version angles measurement option per clinical preference. Introduction of optional ability to save and/or retrieve case specific data via remote or manual transfer.

Indications for Use:

OrthoGrid Hip AI® 4.0 is an image-processing software indicated to assist in the positioning of Total Hip Replacement components. The software uses Artificial Intelligence (AI) to allow real-time initialization of grid placement relative to the bone structures of interest in C-arm fluoroscopic images to assist in precisely positioning Total Hip Replacement components intraoperatively by measuring their positions. Artificial Intelligence will only offer automated initialization of grid placement if the points of interest can be identified from radiology 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.

Contraindications:

OrthoGrid Hip AI® 4.0 may not be suitable for use in cases where clear fluoroscopic images cannot be obtained, and the clinician is unable to identify key landmarks, such as the Lesser Trochanters or Teardrops:

- This may be due to patient anatomic abnormalities.
- This may be due to surgical technique, for example, excessive acetabular reaming resulting in the inability to visualize the radiographic Teardrop.
- This may be due to operating room equipment in use, such as the size of the operating table limiting the tilt of the C-arm, and therefore the detection of Teardrops.

Substantial Equivalence:

Category	Subject Device OrthoGrid Hip AI 4.0 (K260077)	Predicate Device PhantomMSK Hip (K210136)	Relationship	Notes
Device	Automated radiological image processing software	System, image processing, radiological	Similar	The device is updated as the subject device uses Artificial Intelligence to

Category	Subject Device OrthoGrid Hip AI 4.0 (K260077)	Predicate Device PhantomMSK Hip (K210136)	Relationship	Notes
				automatically identify the anatomical landmarks, whereas the predicate device requires the user to manually identify and place points of interest on fluoroscopic images. Differences between the devices do not raise new questions of safety and effectiveness and verification and validation activities demonstrate that the subject device is at least as safe and effective as the legally marketed predicate device.
Product Code	QIH	LLZ	Similar	The product code is updated to reflect the subject device's use of Artificial Intelligence to automatically identify the anatomical landmarks, whereas the predicate device requires the user to manually identify and place points of interest on fluoroscopic images. Differences between the devices do not raise new questions of safety and effectiveness and verification and validation activities demonstrate that the subject device is at least as safe and effective as the legally marketed predicate device.
Regulation	21 CFR 892.2050	21 CFR 892.2050	Identical	
Regulation Description	Medical image management and processing system	Medical image management and processing system	Identical	
Device Class	II	II	Identical	
Classification Panel	Radiology	Radiology	Identical	

Category	Subject Device OrthoGrid Hip AI 4.0 (K260077)	Predicate Device PhantomMSK Hip (K210136)	Relationship	Notes
Intended Use	Image-processing software intended to assist in the intra-operative positioning of total hip replacement components during direct anterior total hip arthroplasty (THA) procedures.	Image-processing software intended to assist in the intra-operative positioning of total hip replacement components during direct anterior total hip arthroplasty (THA) procedures.	Identical	
Indications for Use	OrthoGrid Hip AI® 4.0 is an image-processing software indicated to assist in the positioning of Total Hip Replacement components. The software uses Artificial Intelligence (AI) to allow real-time initialization of grid placement relative to the bone structures of interest in C-arm fluoroscopic images to assist in precisely positioning Total Hip Replacement components intraoperatively by measuring their positions. Artificial Intelligence will only offer automated initialization of grid placement if the points of interest can be identified from radiology 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.	PhantomMSK Hip is an image-processing software indicated to assist in the positioning of Total Hip Replacement and Hip Preservation components. It is intended to assist in precisely positioning Total Hip Replacement and Hip Preservation 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. 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.	Similar	The Indications for Use statement has been updated to reflect that the subject device utilizes AI to automatically identify the anatomical landmarks. Differences between the devices do not raise new questions of safety and effectiveness and verification and validation activities demonstrate that the subject device is at least as safe and effective as the legally marketed predicate device.
Principle of Operation	A fluoroscopic image is acquired from a C-arm by the software and displayed outside the sterile field, where the	A fluoroscopic image is acquired from a C-arm by the software and displayed outside the sterile field, where the	Identical	

Category	Subject Device OrthoGrid Hip AI 4.0 (K260077)	Predicate Device PhantomMSK Hip (K210136)	Relationship	Notes
	image analysis tools can be used at the surgeon's discretion.	image analysis tools can be used at the surgeon's discretion.		
Image Modality	Uses intraoperative fluoroscopic images acquired from a C-arm.	Uses intraoperative fluoroscopic images acquired from a C-arm.	Identical	

Summary of Nonclinical Performance Data:

Verification and Validation Testing for OrthoGrid Hip AI® 4.0 was conducted with the following aspects:

- Performance Tests: Performance tests documented to ensure the performance of the implemented features and verify related design inputs.
- Usability Engineering: Performance of the system in regard to human factors engineering.
- Validation: Validation performed to validate related user needs, intended use and substantial equivalence.
- Software Testing: Software tests were conducted to satisfy requirements of the FDA Guidance for the Content Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software was considered a “Enhanced” level of concern. The testing demonstrates the subject device OrthoGrid Hip AI® 4.0 does not raise any new issues of safety and effectiveness as compared to the predicate device.
- Cybersecurity Testing: Cybersecurity tests were conducted and successfully met requirements per FDA Guidance “Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions”.

Description of AI Functionality and its Integration in the System:

The OrthoGrid Hip AI® 4.0 system incorporates Machine Learning (ML) models that operate on 2D fluoroscopic images to support intraoperative AP Pelvis and AP Hip workflows. The AI models identify landmarks, anatomy, and Total Hip Arthroplasty (THA) implants, which are used to initialize software functions within the system.

These AI outputs are used to automatically initialize software tools that assist with:

- Leg length and offset measurements.
- Cup version and Cup inclination measurements using the trans-teardrop reference line.
- Scene identification to assist workflow progression.
- Anatomic orientation/alignment and positioning within an image.
- Femoral shaft alignment for the AP Hip workflow Overlay feature.

User Control and Override:

The detected scene type can be manually overridden by the user at any time. All AI-identified landmarks that impact system measurements are visible and fully editable, allowing the user to

manually adjust landmark positions in real time at any stage of the procedure. The system automatically updates measurements and calculations immediately based on the user's input.

The OrthoGrid Hip AI® 4.0 outputs are intended to assist, not replace, professional clinical judgment. The operating physician is responsible for reviewing, verifying, and as needed, adjusting all AI-identified landmarks and AI-driven measurements, and retains full responsibility for final clinical decisions.

ML Models Input/Output:

The ML models' input is a 2D fluoroscopic intra-operative anteroposterior (AP) or near AP image showing the pelvis and/or proximal femur, captured from compatible C-Arm systems.

The models generate either segmentation of relevant anatomy (femur) or implant (cup, stem) or landmark positions (e.g., Teardrops, Lesser Trochanters).

ML model outputs are transformed into user-controllable elements, such as landmark positions (e.g., AP landmarks and cup landmarks), femur axis alignment, and inputs used for initial scene selection. These elements are presented to the user at the appropriate workflow stage. Users can interact with these elements, which can be reviewed and manually adjusted as needed to ensure clinical accuracy.

Model Architecture:

The OrthoGrid Hip AI® 4.0 ML models use deep learning architectures, including Convolutional Neural Networks (CNNs) and Transformer-based models. CNN- and Transformer-based models are used for anatomy and implant segmentation, while Transformer-based models are used for landmark detection. All models are optimized for analysis of 2D fluoroscopic images to support landmark identification and anatomy and implant segmentation.

Model Development Summary:

The OrthoGrid Hip AI® 4.0 system incorporates Machine Learning (ML) models trained, and tested using real-world, de-identified fluoroscopic images collected from five geographically distinct clinical sites within the United States. The data reflect THA procedures and capture the complexity of intraoperative imaging and realistic surgical conditions consistent with the device's intended use.

The ML models were developed using real THA fluoroscopic images. No synthetic images were used. **Table 1** summarizes the datasets used for each OrthoGrid Hip AI® 4.0 models, including the number of patients, number of images, and the approximate percentage of data used for training, tuning, and tuning evaluation (held out for technical performance testing) to ensure objective evaluation and reliable model performance.

Table 1: AI Models Development Dataset. Tuning Evaluation sets were held out from training.

ML Model	# Patients	# Images	Training, Tuning, Tuning Evaluation (% of Patients)
Landmark	301	15990	84% – 6% – 10%
Implant	389	16476	82% – 6% – 12%
Femur	502	23484	76% – 12% – 12%

In addition to technical performance testing on tuning evaluation datasets, the AI models were clinically validated using cadaveric specimens with known demographic characteristics. These images were captured under controlled simulated THA surgical conditions to reflect the intended clinical environment.

ML Model Performance on Tuning Evaluation Dataset:

The AI models were evaluated on the tuning evaluation dataset, and the results for the tested sample within the study conditions are summarized in **Table 2** in terms of Accuracy, Sensitivity and Specificity.

Table 2 : Reference VS AI Predictions – ML Models: Accuracy, Sensitivity, and Specificity

ML Model	Accuracy $\pm$ STD	Sensitivity	Specificity	Sample size N (Patients, Images)
Left & Right Teardrop (Pixel)	1.6 ± 2.1	100%	99%	N= (29, 1542), study conditions
Left & Right Lesser Trochanter (Pixel)	2.8 ± 4.5	98%	96%	N= (29, 1542), study conditions
Implant	$95 \pm 5\%$	100%	99%	N= (45, 1923), study conditions
Femur	$98 \pm 3\%$	100%	100%	N= (60, 2393), study conditions

Notes:

- **Accuracy:** Indicates how closely AI predictions match the reference. Evaluated using distance differences for landmarks or the spatial overlap for implant and anatomy models.
- **Sensitivity (Recall):** Reflects the ability of the AI to correctly identify true landmarks or anatomy or implant.
- **Specificity:** Reflects the ability of the AI to correctly ignore areas where landmarks or anatomy or implant is absent.
- **Sample size N:** Values are presented as (number of patients, number of images)

ML Model Performance on Clinical Validation Dataset:

ML Models Outputs

The performance of the three integrated ML models' outputs was evaluated against clinical Ground Truth (GT) generated by three qualified orthopedic surgeons, whose inter-surgeon error variability was quantified to establish the validation threshold. This threshold is based on typical differences observed between surgeons' measurements, defined as the value below which 97.5% of these differences fall, representing the natural range of clinical measurement variability. AI models were considered validated when their mean error, calculated with respect to the GT, remained at or below this value. The tuning and evaluation datasets included: Landmark and Implant Models: 84 THA surgical cases, 342 images; Anatomy Model: 51 THA surgical cases, 182 images.

All measures met the validation criteria for the tested sample size and study conditions, demonstrating that the AI outputs are consistent, reliable, and fall within the variability range of

the observed errors among surgeons in clinical settings as reported in **Table 3**. The detection rate (i.e. Sensitivity) of all AI models was 100% under study conditions.

Table 3: Manual vs AI Predictions – Global Average Results Compared to Surgeon Ground Truth for Evaluated Measures (Teardrops, Lesser Trochanters, Cup Positioning, and Femur Alignment Angles)

Measure	Mean Error (Accuracy) $\pm$ STD	Validation Threshold	Agreement Rate AI vs Manual	Sample size N (cases, images)
Teardrop (mm)	0.95 $\pm$ 0.73 (Right)	3.70	100%	N= (84, 253), study conditions
	0.64 $\pm$ 0.49 (Left)	3.22	100%	N= (84, 245), study conditions
Lesser Trochanter (mm)	2.02 $\pm$ 1.35 (Right)	4.84	100%	N= (84, 189), study conditions
	1.54 $\pm$ 1.16 (Left)	3.77	100%	N= (84, 199), study conditions
Cup Version (°)	1.38 $\pm$ 0.95	3.48	100%	N= (84, 255), study conditions
Cup Inclination (°)	0.44 $\pm$ 0.43	2.42	100%	N= (84, 255), study conditions
Femur Alignment Angle (°)	1.27 $\pm$ 0.88	2.85	98.04%	N= (51, 182), study conditions

Notes:

- **Mean Error:** Difference between AI predictions and manual ground truth, where the ground truth is defined as the average measurement from the three surgeons.

The AI models were clinically validated in a statistical study using data that may not fully represent all patient populations. Key demographic representation included:

- **Gender:** 57% female, 43% male
- **Age:** Concentrated in 60–79 (61%); limited representation under 50 (7%)
- **C-Arm detector size:** Most commonly 12-inch (40.5%), with smaller proportions of 9-inch (26.2%) and flat-panel detectors (33.3%)

The results showed that the AI models met the predefined performance criteria, with a statistical strength of 95% confidence and 90% reliability, and no systematic deviations were observed across the evaluated factors.

Performance results along with other factors were also collected and reported, including:

- **BMI:** Concentrated under 25 (61%), with limited representation over 35 (4.5%).
- **Ethnicity:** Predominantly White (90.5%), with limited representation of Asian (2.4%) and Hispanic (7.1%) participants.
- **Bone disease:** Most common condition is arthritis (29.8%), with smaller representation of osteoporosis (14.3%).

While some of these additional subgroups had limited sample sizes and could not support statistically significant conclusions, the data was carefully reviewed and ML model performance remained consistent, as no systematic bias or performance degradation was observed across these categories, supporting confidence in the overall AI performance results. However, performance in underrepresented populations has not been independently validated. Physicians should exercise due judgment when interpreting AI outputs for patients whose characteristics differ substantially from the validation dataset.

AI Integrated with OrthoGrid Hip AI® 4.0:

A total of 102 paired system output measurements were compared between fully automatic AI outputs and manually adjusted measurements all using different workflows, AP Pelvis or AP Hip workflows (Ipsilateral or Contralateral).

Of these, 89.2% were concordant, while 10.8% showed some degree of discrepancy. The maximum observed differences were ≤ 3 mm for Leg Length and Offset measurements and $\leq 1^\circ$ for Cup inclination and anteversion angles. This demonstrates a high degree of surgeon agreement with AI predictions, supporting confidence in model performance under studied conditions.

ML Models Limitations:

AI performance characteristics were established under controlled validation study conditions and the intended use environment. Actual clinical performance may vary depending on factors such as patient anatomy, surgical technique, and intraoperative conditions. Atypical imaging conditions/positions, including landmarks near image boundaries or partially outside the field of view, unusual occlusions, or poor image quality (e.g., blurred, contrast) may result in inaccurate or failed landmarks detection.

AI Performance Monitoring:

The ML Models are locked/frozen and do not engage in continuous or adaptive learning once deployed. The locked model design ensures consistent, validated performance characteristics throughout the product lifecycle.

OrthoGrid Hip AI® 4.0 ML performance is monitored after release. Updates to the ML models may be applied through a controlled software change, including a full software version update, when supported by new data or validated findings.

Conclusion:

The conclusions drawn from the nonclinical testing demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device, PhantomMSK Hip (K210136).