Orthopedic Driven Imaging, LLC
Michael Mccaig
General Manager
4424 NW 13th St., Suite B-6
Gainesville, FL 32609

May 8, 2026

Re: K260321
Trade/Device Name: HipGuide (V 1.0.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 2, 2026
Received: April 2, 2026

Dear Michael Mccaig:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K260321

Please provide the device trade name(s).

HipGuide (V 1.0.0.0)

Please provide your Indications for Use below.

HipGuide is a medical device software application designed to assist surgeons in evaluating implant positioning, alignment, and anatomical relationships during hip replacement procedures. HipGuide supports intra-operative clinical decision making by providing visual overlays or measurements taken manually on fluoroscopic images. It is not intended to replace the surgeon's judgment or serve as a diagnostic device. Rx only.

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

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

510(k) #:

510(k) Summary

Prepared on: 2026-01-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Orthopedic Driven Imaging, LLC
Applicant Address	4424 NW 13th Street, Suite B-6 Gainesville FL 32609 United States
Applicant Contact Telephone	(901) 603-1309
Applicant Contact	Dr. Michael McCaig
Applicant Contact Email	mac@orthodriven.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HipGuide (V 1.0.0.0)
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
K210136	PhantomMSK Hip	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

HipGuide is a software application that provides calibrated measurement overlays, alignment guides, and visual reference markers on fluoroscopic images to support intraoperative decision-making during orthopedic procedures, including hip replacement surgery. HipGuide's principle of operation is manual, user-controlled placement and adjustment of points, lines, and visual guides directly on the displayed fluoroscopic image, enabling assessment of distances and angles without altering the underlying image data. HipGuide is used during procedures involving the hip and surrounding anatomy and does not contact the patient or interact with implants. The user interface consists of on-screen tools that allow surgeons to create, move, and remove measurement elements using standard system controls. The device interacts only with the host imaging system by displaying overlays on top of the live or captured fluoroscopic image and does not modify, store, or transmit patient data.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

HipGuide is a medical device software application designed to assist surgeons in evaluating implant positioning, alignment, and anatomical relationships during hip replacement procedures. HipGuide supports intra-operative clinical decision making by providing visual overlays or measurements taken manually on fluoroscopic images. It is not intended to replace the surgeon's judgment or serve as a diagnostic device. Rx only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device utilizes the same principle of operation as the predicate device as they are both designed to make measurements using intra-operative radiographic images acquired by a mobile c arm.

HipGuide is substantially equivalent to the predicate device PhantomMSK Hip (K210136) with respect to intended use, technological characteristics, and performance.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate and subject devices are similar in the types of measurements they make and in the environments in which they are used, namely, to landmark and make measurements in connection with total hip arthroplasty (THA) procedures using images acquired by a mobile C-arm in the operating room. The predicate device is mounted on a monitor cart connected to the C-arm video output, whereas the subject device is operated directly on the C-arm. The predicate device can use a grid to correct image distortion caused by image intensifiers and can work with flat-panel detectors. The subject device works with images produced by flat-panel detectors, which have twice the image area of a 12-inch image intensifier, providing images wide enough to capture both hips at once without requiring grid calibration. The predicate device offers algorithmic automated landmarking with manual adjustments and AI-powered software to simplify landmarking and measurements. The subject device relies on manual landmarking and the placement of measurement tools.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The bench testing was performed in connection with the Software Verification Testing. The Bench Testing Report provides a summary of those activities and compares those results to several scientific publications on this subject to provide evidence that the measurement accuracy of the subject device is well within the limits suggested by the literature. No guidance documents or FDA recognized consensus standards were used.

Measurement Accuracy Testing: Nearly 100 linear and angular measurements were evaluated using calibrated test objects with known dimensions and angular positions. HipGuide demonstrated a measurement accuracy of ±5 mm for linear measurements and ±5° for angular measurements. These results support that HipGuide's measurement performance is consistent with the predicate device and suitable for its intended intraoperative use.

Not Applicable