January 29, 2025

Gyder Surgical Pty Ltd.
% David Rutledge
Consultant
Global Strategic Solutions, LLC
1631 Mercy Street
Mountain View, California 94041

Re: K243387
Trade/Device Name: GYDER® Hip System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 26, 2024
Received: October 31, 2024

Dear David Rutledge:

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,

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)*
K243387

Device Name
GYDER® Hip System

Indications for Use *(Describe)*

Indications For Use

The GYDER® Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopaedic surgical procedures. The GYDER® Hip Navigation System facilitates the accurate positioning of the acetabular cup only during Anterior Hip Arthroplasty approaches with the patients in supine position.

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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K243387 510(k) Summary

Applicant Information:
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Device Name: GYDER® Hip System
Common Name: Stereotaxic Instrument
Regulation name: Orthopedic Stereotaxic Instrument
Classification: Class II
Product Code: OLO
Submission Type: Traditional 510(k), New Device
Regulation Number: 21 CFR 882.4560
Predicate Device: OrthAlign Plus System (K130387)

Indications For Use

The GYDER® Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopaedic surgical procedures. The GYDER® Hip Navigation System facilitates the accurate positioning of the acetabular cup only during Anterior Hip Arthroplasty approaches with the patients in supine position.

Intended Use

The GYDER® Hip Navigation System is intended to be used only during Anterior Hip Arthroplasty approaches with the patients in supine position, with acetabular cups that are uncemented and allow for post-impaction measurement and confirmatory measurement.

Device Description

The GYDER® Hip System is a computer controlled non-invasive surgical tool to aid navigation during Total Hip Arthroplasty via the Anterior Approach. The system includes both reusable and consumable components, designed to work together to assist the surgeon in positioning the acetabular cup in the intended orientation during primary or revision Total Hip Arthroplasty.

Substantial Equivalence

The GYDER® Hip Navigation System is substantially equivalent to the OrthAlign Plus System predicate device in the Hipalign configuration based on the analysis of Clinical, Technical, and Biological characteristics and performance data that includes bench and cadaver based tests.

Comparison between GYDER® Hip System and the Predicate Device

Table 1. Comparison of Subject Device to Predicate Device

Attribute	**Subject Device:** **GYDER® Hip Navigation System**	**Predicate Device** **OrthAlign Plus® in the HipAlign® configuration**	**Comparison Differences /Similarities**
510(k) Number	New application	K130387 [3] Orthalign Plus® in the HipAlign® configuration for Total Hip Arthroplasty (THA).	N/A
FDA Regulation	882.4560	882.4560	EQUIVALENT.
Product Code	OLO: Orthopedic Stereotaxic Instrument	OLO: Orthopedic Stereotaxic Instrument	EQUIVALENT.
Product Classification	Class II	Class II	EQUIVALENT.
Use	Prescription Use/ Rx Only	Prescription Use/ Rx Only	EQUIVALENT.
Intended User	Primary user: Orthopedic Surgeon Secondary user: Surgical Assistant / Nurse	Primary user: Orthopedic Surgeon Secondary user: Surgical Assistant / Nurse	EQUIVALENT.
Use Environment	Hospital / Operating Theatre	Hospital / Operating Theatre	EQUIVALENT
Patient Population	Patients undergoing Total Hip Arthroplasty: ● Anterior Approach with patient supine.	Patients undergoing Total Hip Arthroplasty. ● Anterior Approach with patient supine ● Posterior Approach with patient lateral decubitus.	EQUIVALENT for Anterior Approach. GYDER® Hip Navigation System does not support Posterior Approach.

Attribute	Subject Device: GYDER® Hip Navigation System	Predicate Device OrthAlign Plus® in the HipAlign® configuration	Comparison Differences /Similarities
Indications for Use	The GYDER® Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The GYDER® Hip Navigation System facilitates the accurate positioning of the acetabular cup relative to the alignment axes. Example orthopedic surgical procedures include: ● Total Hip Arthroplasty: Anterior The GYDER® Hip Navigation System for supine patient registration is indicated for use: ● In Hip Arthroplasty surgical procedures; ● with acetabular cups that are uncemented and allow for post-impaction measurement and confirmatory measurement.	The HipAlign® System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The HipAlign® System facilitates the accurate positioning of implants, relative to the alignment axes. Example orthopedic surgical procedures include but are not limited to: ● Total Hip Arthroplasty: Anterior/Posterior	EQUIVALENT for Anterior Approach. GYDER® Hip Navigation System does not support Posterior Approach.
Operating Conditions	Specified storage and operating conditions for surgical environments ● Hospital use, normal ambient conditions of temperature, and lighting ● Within the sterile field of an operating theatre ● Temperature: 16 to 24°C ● Humidity: 20 to 60% RH (non-condensing) ● Pressure: 70 kPa to 106 kPa	Specified storage and operating conditions for surgical environments ● Hospital use, normal ambient conditions of temperature, and lighting ● Within the sterile field of an operating theatre ● Temperature: 15 to 25°C ● Humidity: 10 to 70% RH (non-condensing) ● Pressure: 70 kPa to 106 kPa	EQUIVALENT
Storage and Transportation Conditions	Specified storage conditions for typical transport environments: ● Temperature: -30 to 60°C ● Humidity: 15 to 90% RH (non-condensing) ● Pressure: 50 kPa to 106 kPa	Specified storage conditions for typical transport environments: ● Temperature: -30 to 60°C ● Humidity: 10 to 95% RH (non-condensing) ● Pressure: 60 kPa to 101 kPa	EQUIVALENT
System Characteristics	Computer-assisted navigation system	Computer-assisted navigation system	EQUIVALENT
Control Mechanism	Electronics attached to movable instruments, placed in specific procedural positions, on or in contact with bony anatomy, for recording sensor data.	Electronics attached to movable instruments, placed in specific procedural positions, on or in contact with bony anatomy, for recording sensor data.	EQUIVALENT

Attribute	Subject Device: GYDER® Hip Navigation System	Predicate Device OrthAlign Plus® in the HipAlign® configuration	Comparison Differences /Similarities
Operating Principle/Registration of Anatomy	Patient registration referencing Anterior Pelvic Plane landmarks using a non-invasive mechanical device. Sensors are attached to moveable instruments placed in specified procedural positions, on or in contact with bony anatomy, for recording data. Measurements to confirm the final implant angles after implantation has been completed.	Patient registration referencing Anterior Pelvic Plane landmarks using invasive pins. Sensors are attached to moveable instruments placed in specified procedural positions, on or in contact with bony anatomy, for recording data. Measurements to confirm the final implant angles after implantation has been completed.	SIMILAR
Measurement and Navigation	● Computer derived values. ● Inertial Measurement Unit (IMU containing Accelerometer and rate gyroscope) measurement of orientation of instrument.	● Computer derived values. ● Inertial Measurement Unit (IMU containing Accelerometer and rate gyroscope) measurement of orientation of instrument.	EQUIVALENT
Main Components	<u>Sensors and Software:</u> ● Navigation Unit (reusable computer) ● Navigation and measurement software <u>Single-Use items:</u> ● Clam Shell (navigation unit sterile enclosure) ● ASIS Markers ● APP Ruler <u>Re-usable Instrument sets:</u> ● Orthopaedic Brace and Impactor Set ● Impactor (as manufactured by Mac Surgical)	<u>Sensors and Software:</u> ● Navigation Unit (reusable computer unit) ● Navigation and measurement software <u>Single -Use items</u> ● Single-use sensor <u>Re-usable Instrument sets:</u> ● Pelvic Pins and instrument set ● Impactor	EQUIVALENT.
User interface	Integrated Graphical User Interface. The device uses algorithms to convert sensor outputs into spatial coordinates, providing graphical and numerical representations of the instruments relative to patient anatomy on the NU screen.	Integrated Graphical User Interface. The device utilizes algorithms to convert sensor outputs into spatial coordinates, providing graphical and numerical representation of instruments relative to patient anatomy on the computer screen.	EQUIVALENT.
Sterility (incl. method)	● Navigation Unit protected by sterile Clam Shell and is not exposed to biological contaminants. ● Clam Shell and ASIS Markers: EO sterilization. ● Orthopaedic Brace, Impactor Bracket, Impactor: Steam/autoclave sterilization.	● Navigation Unit: EO sterilization. ● Instruments: autoclave sterilization	EQUIVALENT
Energy Sources	● Navigation Unit: ● DC battery power ● Other components are passive	● Navigation unit and reference sensor: ● DC battery power	EQUIVALENT.

Attribute	Subject Device: GYDER® Hip Navigation System	Predicate Device OrthAlign Plus® in the HipAlign® configuration	Comparison Differences /Similarities
		● Other components are passive	
Analytical Studies	● Cadaver study performed.	● Cadaver study performed.	EQUIVALENT.

Performance Data

Device performance testing confirms that the GYDER® Hip Navigation System can be used according to its intended use. The GYDER® Hip Navigation System has been verified and validated according to Gyder Surgical procedures for product design and development. Performance testing addressed the functionality and surgical procedure workflows/steps as defined in the GYDER® Hip System Instructions for Use and demonstrates that the GYDER® Hip System is as safe, as effective, and performs as well as the predicate device [OrthAlign Plus® System (K130387)].

Non-Clinical Testing

Testing included:

• Software verification and validation to ensure the integrity of the code and functionality and reliability of the software in various use sequences.
• System hardware verification/validation testing to ensure the device meets their functional requirements.
• Instrumentation cleaning, sterilization and shipping validations for the specified processes.
• System components biocompatibility assessment per ISO 10993-1 (2018).
• System accuracy testing by bench testing for angle measurement accuracy including using ASTM F2554-18.
• System usability testing for formative and summative testing.
• Simulated use testing in cadaver with advising surgeons to validate the system meets requirements for user needs and usability in a simulated use environment.

This testing regime demonstrates that the subject device is as safe and performs as well as the predicate device.

Clinical Testing

No clinical trial required. Simulated use testing on cadavers performed

Conclusion

The GYDER® Hip System is substantially equivalent to the predicate device OrthAlign Plus® System (K130387). Testing against the FDA consensus performance standard (ASTM F2554-18) and clinical

validation using cadaver models has demonstrated that the GYDER® Hip System is as safe and as effective as the predicate device.