December 9, 2022

Hangzhou Lancet Robotics Co., Ltd.
% Gordon Shu
Director of Regulatory Affairs
Shanghai Zhirui Management Consulting Co., Ltd.
No. 741 Yao Zhou Road, Xin Cun, Chong Ming district
Shanghai, Shanghai 202150
China

Re: K220774
Trade/Device Name: RobPath® Total Hip Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 7, 2022
Received: November 7, 2022

Dear Gordon Shu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220774

Device Name
RobPath® Total Hip Application

Indications for Use *(Describe)*
The RobPath® Total Hip Application is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures. The RobPath® Total Hip Application is indicated for use in a surgical hip procedure in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:
• Total Hip Arthroplasty (THA)

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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510(k) Summary of Safety and Effectiveness

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the RobPath-THA-001 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

Date Prepared:	December 9, 2022	
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Submission correspondent:	Shanghai Zhirui Management Consulting Co., Ltd. No. 741 Yao Zhou Road, Xin Cun, Chong Ming district Gordon Shu Director of Regulatory Affairs Phone: +86-13656237738 E-mail: jian_shu2002@hotmail.com	
Subject Device:	RobPath® Total Hip Application (RobPath-THA-001)	
Classification:	Classification name:	Orthopedic Stereotaxic Instrument
	Classification Regulation:	21CFR 882.4560
	Review Panel:	Orthopedic
	Device Class:	Class II
	Product Code:	OLO
Predicate Device	Trade name:	MAKO Total Hip Application
	Manufacturer:	Mako Surgical Corp.
	510(k) Clearance:	K193128
	Classification Regulation:	21CFR 882.4560
	Classification name:	Orthopedic Stereotaxic Instrument
	Review Panel:	Orthopedic
	Device class	Class II
	Product Code:	OLO
Device Description:	The proposed RobPath® Total Hip Application is a semi-active robotic system. Pre-operative CT imaging is used to generate a 3D model of the native hip joint. An initial plan is created using selected CT landmarks and superimposed onto the 3D reconstruction. The surgeon is then able to fine-tune this to ensure optimal templating of component size and alignment, thus allowing the desired restoration of hip biomechanics, bone coverage, component positioning and leg-length	

	correction. The robotic arm is not fully automated but based on haptic feedback, so the surgeon retains partial control during the implantation.
Indications for Use:	The RobPath® Total Hip Application is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures. The RobPath® Total Hip Application is indicated for use in a surgical hip procedure in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include: • Total Hip Arthroplasty (THA)
Summary of Technological Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • The subject and predicate devices are intended to assist the surgeon in providing software defined spatial boundaries for orientation • The subject and predicate devices assist in intraoperative navigation of the patient's anatomy and are utilized to facilitate implant positioning. • The subject and predicate device consists of the same major components including Robotic Arm, Guidance Module, Optical Tracking system, Foot switch, Medical electric bone drill and Surgical Instruments. • The instrument features and functions of the subject and predicate devices are intended to allow assembly of the sensors, to attach the subject bones, to register or digitize the applicable landmarks, and to adjust the alignment of provided guides.
Summary of Non-Clinical Performance Data:	The proposed **RobPath-THA-001** comply with the following international and FDA-recognized consensus standards: • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD). • IEC 60601-1-2 Edition 4.0: 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic disturbances -Requirements and Tests

	• IEC 60601-1-6 Edition 3.1: 2013-10 Medical Electrical Equipment -- Part 1-6: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Usability • IEC 62366-1 Edition 1.0: 2015-02 Medical devices – Part 1: Application of usability engineering to medical devices • IEC 80601-2-77 Edition 1.0: 2019-07 Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment • ASTM F2554-18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems • IEC 62304 Edition 1.1: 2015 Medical device software – Software life cycle processes. • ISO14971 Edition 2: 2007-03-01 Medical devices – Application of risk management to medical devices. • ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood • ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization • ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

	• ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood • Guidance for Industry and FDA Staff — Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005) • Guidance for Industry and FDA Staff — Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014) • Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued June 16, 2016) • Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016) • Guidance for Industry and FDA Staff –Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (issued March 17, 2015) Non-Clinical verification and validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications, and the risk management results. Therefore, the proposed **RobPath-THA-001** are substantially equivalent to the currently marketed predicate device MAKO Total Hip Application (K193128) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **RobPath-THA-001** did not require clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.
Substantial Equivalence Conclusion:	The proposed **RobPath-THA-001** and the currently marketed predicate device MAKO Total Hip Application (K193128) have the same indications for use. The proposed **RobPath-THA-001** are substantially equivalent to the currently marketed predicate device MAKO Total Hip Application (K193128) in terms of design features, fundamental scientific technology, indications for use, and

	safety & effectiveness. Any differences do not raise new questions of safety and effectiveness The results of these tests demonstrate that the proposed **RobPath-THA-001** meet the acceptance criteria and is adequate for its intended use.