June 18, 2023

Sinovation (Beijing) Medical Technology Co., Ltd
% Giselle Zhang
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K220072
Trade/Device Name: Sinobot X1
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 15, 2023
Received: May 18, 2023

Dear Giselle Zhang:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.06.18 10:18:57 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220072

Device Name
Sinobot X1

Indications for Use *(Describe)*

The Sinobot X1 is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode). The device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery 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.

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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	Sinovation (Beijing) Medical Technology Co., Ltd Rm 401, Bld 12-1, No.26 Yongwang West Road, Z- park Daxing, Beijing, Beijing 102600 P.R.China Telephone: Fax: N/A Manman Xu RA Specialist xumanman@sinovationmed.com
Contact:	Giselle Zhang Regulatory Consultant Emergo Global Consulting, LLC 2500 Bee Cave Road, Building 1, Suite 300 Austin, Texas 78746 USA Telephone: (512) 327-9997 Fax: (512)327-9998 LST.AUS.ProjectManagement@ul.com
Date Summary Prepared:	June 18, 2023

5.2 Name of the Device

Trade/Device Name:	Sinobot X1
Common Name:	Stereotaxic Instrument
Classification Name:	Neurology
Review Panel:	Neurology (NE)
Regulation:	882.4560
Class:	Class II
Product Code:	HAW

5.3 Equivalence Claimed to Predicate Device

The Sinovation is equivalent to the ROSA ONE Brain application (K200511), manufactured by Medtech S.A.

5.4 Indications for Use Statement

The Sinobot X1 is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments

(biopsy needle, stimulation or recording electrode). The device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate.

5.5 Device Description

The Sinobot X1 device is a computer-aided, robotized image-guided interactive surgical system. The system integrates medical image processing technology with robotic surgery technology to assist the surgeon during brain surgeries. The system allows the surgeon to utilize the spatial positioning technology to pre-plan the instruments or implants on medical images and provide stable, precise and reproducible guidance in accordance with the planning. The device consists of a robotic stand with a compact robotic arm and a touch screen. The robotic arm can attach to different types of instruments and be changed based on the intended surgical procedures. For different surgical procedures a biopsy needle, stimulation or recording electrode could be attached to the device.
The 3D Optical scanner is an optical device combined by a projector and a visible light camera. Which provide a high-resolution point cloud scanning of patients' facial skin surface in order to perform patient registration.

5.6 Substantial Equivalence Discussion

The following table compares the Sinovation to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5.1: Comparison Table

Attribute	Sinovation Sinobot X1	ROSA ONE 3.1.3.2 Brain Application (K200511)	Comparison
Manufacturer	Sinovation (Beijing) Medical Technology Co., Ltd	Medtech S.A	N/A
Product Code	HAW	HAW	Same
Regulation Number	882.4560	882.4560	Same
Indications for Use	The Sinobot X1 is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode). The	The device is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is	Same

	device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate.	indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate.	
Mechanism of Action	Pre-Operative Planning Intra-Operative Registration Intra-Operative Guidance	Pre & intraoperative images Surgical planning Patient Registration Guidance of instruments	Same Only the description is different.
Where Used	Neurosurgical operating room	Neurosurgical operating room	Same
User	Neurosurgeon	Neurosurgeon	Same
Anatomical Site	Head	Head	Same
Images Type	3D MRI / CT	3D MRI / CT	Same
DICOM Compliance	Yes	Yes	Same
Integrated Planning Software	Stereotactic Planning System Software	ROSANNA BRAIN (Medtech)	Different All software functions and features are similar.
Trajectory Planning Parameters	Parameters for planning trajectories: entry point, target point, length of the instrument, diameter, name	Parameters for planning trajectories: entry point, target point, length of the instrument, diameter, name, security radius (10mm by default), security aperture (10° by default)	Different
Trajectory Definition (Endoscopy Module)	No endoscopic module	Parameters for planning trajectories: entry point, target point, length of the instrument, diameter, name, security radius (10mm by default), security aperture (10° by default)	Different The subject device does not contain endoscopic module, the difference of the two devices will not raise concerns related to the safety and effectiveness.
Save/Load Planning	Yes	Yes	Same
Patient Registration Methods	Fiducial markers (bone) Optical registration device	Fiducial markers (skin, bone) Optical registration device	Same

		Stereotactic frame (fiducials mounted on the frame)	
Fiducial Markers Registration with Pointer Probe	Yes	Yes	Same
Surface Matching Registration with Optical Distance Sensor	Yes	Yes	Same
Laser Class for Optical Registration	Class 2 laser Wavelength - 655nm Maximum Output – 560µW (complies with 21 CFR 1040.10)	Class 2 laser Wavelength – 658 nm Maximum output – 1 mW (complies with 21 CFR 1040.10)	Different Even though the specifications are different, the subject device passed the standards requirements and is safe to use, hence the difference will not raise concerns in safety and effectiveness.
Image-Guided	Yes	Yes	Same
Real Time Display of the Instrument Position	Yes	Yes	Same
Provide Guidance for Surgical Instruments	Yes	Yes	Same
Instrument Guide Position Adjustment	Automatic (robotized)	Automatic (robotized)	Same
Instrument Fixation	Instruments are mounted on robotic arm	Instruments are mounted on robotic arm	Same
Instruments	Instrument holder, holder and adaptors, optical sensor	Instrument holder, endoscope holder and adaptors, optical sensor	Different The instruments of both devices are the same except the endoscopic module, which the subject device does not have. The difference will not affect the use of the device and will not affect

			and raise new risks related to safety and effectiveness of the device.
Instrument Calibration Method	Factory calibration	Factory calibration	Same
Associated Equipment	Navigation Probe (Pointer Probe) Standard Tool Holder (Guider) Microdrive Holder Optical Sensor (Optical Distance Sensor and Optical 3D scanner) Fiducial markers Head holder Frame Registration Plates Frame Adapter Head Holder Adapter	Navigation probe Standard tool holder Endoscope holder Microdrive holder Optical sensor Fiducial markers Head holder Leksell frame registration plates CRW Frame Head Holder Adapter	Different Both the subject device and predicate device shares similar components or associated equipment, only the predicate device contains the endoscopic module, and the difference will not affect the use of the device and will not affect and raise new risks related to safety and effectiveness of the device.
Patient Immobilization	Yes - The device is attached to the head holder or the frame via an adaptor	Yes - The device is attached to the head holder or the frame via an adaptor	Same
Device Mobility	Yes - Mobile stands with wheels; Robotic stand immobilized with stabilization feet	Yes - Mobile stands with wheels; Robotic stand immobilized with stabilization feet	Same
Vigilance System	Yes – foot pedal	Yes – foot pedal	Same
Sterile	Non-sterile and sterile instruments Disposable sterile drapes for the robotic arm and touch screen	Non-sterile and sterile instruments Disposable sterile drapes for the robotic arm and touch screen	Same
Single-Use	No	No	Same
Ac Powered	Yes	Yes	Same
Electrical Safety Testing	IEC 60601 Series of Standards	IEC 60601 Series of Standards	Same

5.7 Non-Clinical Performance Data

To demonstrate safety and effectiveness of Sinovation and to show substantial equivalence to the predicate device, Sinovation completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Sinovation passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Risk Assessment of the Biocompatibility per ISO 10993-1 – Requirements Met
- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Usability per IEC 60601-1-6 – Demonstrates the usability was considered during design
- Usability per IEC 62366-1 – Demonstrates the usability was considered during design
- Software verification and validation per IEC 62304/FDA Guidance – results /conclusion
- Safety of Laser Products per IEC 60825-1 – Passed
- Sterilization validation – demonstrates SAL of 10-6
- Shelf Life Testing – Supports shelf life of 10 years
- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained

Sinovation also conducted the accuracy tests and the data as reported in Table 5.2 below:

Table 5.2 Accuracy Testing Results

Device Performance	Mean	Standard deviation	Confidence interval at 99% confidence level
Positional accuracy [mm]	0.613	0.197	1.205
Angular accuracy [degree]	0.439	0.241	1.163

5.8 Statement of Substantial Equivalence

The Sinobot X1 has the same intended use as the predicate device, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the Sinobot X1 is as safe and effective as the predicate device. Therefore, the Sinobot X1 is substantially equivalent to the predicate device.