March 14, 2025

Moon Surgical
℅ Michael Daniel
Consultant
Daniel & Daniel Consulting
P.O. Box 129
Minden, Nevada 89423

Re: K242323
Trade/Device Name: Maestro System (REF100)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: QZB
Dated: January 14, 2025
Received: January 15, 2025

Dear Michael Daniel:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.03.14 15:18:19 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.

Submission Number *(if known)*

K242323

Device Name

Maestro System (REF100)

Indications for Use *(Describe)*

The Maestro System is intended to hold and position laparoscopes and laparoscopic instruments during laparoscopic surgical procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K242323

Applicant Information:

Date Prepared: March 10, 2025

Name: Moon Surgical

Address: 9 rue d'Enghien

75010 Paris France

Contact Person: Michael A Daniel, Consultant

madaniel@clinregconsult.com

Mobile Number: (415) 407-0223

Device Information:

Device Trade Name: Maestro System

Common Name: Maestro System

Classification Name(s): Endoscope And Accessories

Product Code/ Regulation: QZB 21 CFR 876.1500

Classification: Class II

Predicate Device:

Maestro System, Moon Surgical SAS (K240598)

Autolap System, Medical Surgery Technologies, Ltd. (K152848)

Subject Device Description

The Moon Maestro System is a 2-arm system which utilizes software and hardware to provide support to surgeons for manipulating and maintaining instrument position. Motors compensate for gravitational force applied to laparoscopic instruments, while surgeon control is not affected. Conventional laparoscopic tools are exclusively controlled and maneuvered by the surgeon, who grasps the handle of the surgical laparoscopic instrument and moves it freely until the instrument

is brought to the desired position. Once surgeon hand force is removed, the Maestro system reverts to maintenance of the specified tool position and instrument tip location. This 510(k) is being submitted to implement the ScoPilot feature. ScoPilot is an on-demand, optional, ease-of-use feature of the Maestro System, allowing the laparoscope which is attached to a Maestro Arm to seamlessly follow a desired instrument tip. The surgeon remains in control of laparoscope positioning, without having to disengage from the instrument in their hand, helping maintain surgical flow and focus.

Subject Device Intended Use / Indications for Use

The Maestro System is intended to hold and position laparoscopes and laparoscopic instruments during laparoscopic surgical procedures.

Predicate Device and Subject Device Comparison

The table below compares the Maestro System to the predicate devices.

ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Primary predicate Device)	MST – MEDICAL SURGERY TECHNOLOGIES LTD (Secondary predicate device)	COMPARISON
Device Name	Maestro System	Maestro System	Autolap System	N/A
510(k) Number	Not yet assigned	K221410	K152848	N/A
Product Code / Regulation	QZB / 876.1500 Endoscope And Accessories	FQO / 878.4960 Table Operating-room, Ac-Powered.	GCJ / 876.1500 Endoscope And Accessories	Identical to 2nd predicate
Brief Description	The Moon Surgical Maestro device is an electrically actuated device with movable components intended for laparoscopic surgical procedures to support and position laparoscopic instruments.	Same	The Autolap system is a compact image guided laparoscope manipulator that is designed to hold and position the laparoscope during laparoscopic surgery. Its role is to hold and move the laparoscope under the direct control of surgeon.	Substantially equivalent
Intended Use / Indications for Use	The Maestro System is intended to hold and position laparoscopic Instruments during laparoscopic surgical procedures.	Same	[*The Autolap is used*] for the purpose of holding and controlling the movement of a standard laparoscope or rigid endoscope for General laparoscopic, Gynecologic and Urologic procedures	Substantially equivalent
Technological characteristics				
System basic components	Two motorized Arms that hold and position the laparoscope and/or laparoscopic instruments	Same	A motorized Arm that holds and positions the laparoscope (the Autolap ARM) A control unit that controls the	Substantially equivalent

ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Primary predicate Device)	MST – MEDICAL SURGERY TECHNOLOGIES LTD (Secondary predicate device)	COMPARISON
	Two stages, supporting and positioning the arms A Control Unit that controls the movements of the arms Instrument Coupling A User interface for system setup and feature selection		movements of the ARM A positioning unit connecting the Arm to the operation bed rail on either side A hand-controlled Command Unit that enables the surgeon to move the laparoscope to his/her chosen target location Instrument coupling	
Method of instrument attachment	Mechanical clamp around laparoscopic instrument and mechanical attachment to arm	Same	Same	Identical
Mechanisms involved in physical positioning	Electro-mechanical jointed arms driven by internal motors that follow the physician movements.	Same	Same	Identical
Method of control	Movement of the laparoscope is enabled only upon applied force to the instrument handle. Endoscope can optionally be controlled by selected handheld instruments with Endoscope following instrument tip.	Movement of the laparoscope is enabled only upon applied force to the instrument handle.	Movement of the laparoscope is enabled only upon pressing the button on the joystick command or the Manual Activation Button or be guided by the movement of a designated tool within the field of view.	Substantially equivalent
Endoscope Movement	Manual Control Control algorithm applying motor current for instrument motion triggered by physician direct movement Instrument Based Control	Manual Control Control algorithm applying motor current for instrument motion triggered by physician direct movement	Manual Control Control algorithm applying motor current for instrument Ât motion triggered by physician direct movement	Substantially equivalent

ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Primary predicate Device)	MST – MEDICAL SURGERY TECHNOLOGIES LTD (Secondary predicate device)	COMPARISON
	Image processing algorithms that enable the detection of all surgical tools within the displayed video image and when commanded by the surgeon, follow the movement of the chosen tool.		<u>Instrument Based Control</u> image processing algorithms that enable the detection of all surgical tools within the displayed video image and when commanded by the surgeon, follow the movement of the chosen tool. <u>Joystick control</u> indirect instrument movement communicated via RF signal.	
Video Image Handling	The video image is transferred from the laparoscope camera unit, through the frame grabber, to the Image Processing Algorithm	N/A	The video image is transferred from the laparoscope camera unit, through the frame grabber, to the Image Processing Algorithm	Substantially equivalent
Image Processing Algorithm	The Image Processing Algorithm continuously detects the coordinates of the surgical tools within the video image. Additionally, it calculates the transformation matrix, which correlates to the laparoscope's movement from image to image	N/A	The Image Processing Algorithm continuously detects the coordinates of the surgical tools within the video image. Additionally, it calculates the transformation matrix, which correlates to the laparoscope's movement from image to image	Substantially equivalent
Instrument tip identification	Machine Learning methodology used to develop	N/A	Computer Vision methodology used to develop	Substantially equivalent

ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Primary predicate Device)	MST – MEDICAL SURGERY TECHNOLOGIES LTD (Secondary predicate device)	COMPARISON
software algorithm development method	software algorithm responsible for identifying tool tip. Once developed, this software algorithm is fixed and static and added to the rest of the system software.		software algorithm responsible for identifying tool tip. Once developed, this software algorithm is fixed and static and added to the rest of the system software.	
Alarm and Warning Condition Indicators	The arms and lighthouse of the Maestro System are equipped with eight LEDs that convey information about the system's status and conditions. If necessary, alerts, notifications, and fault messages or graphics are displayed on the Touchscreen simultaneously to indicate the system's current status.	Same	Alerts, notifications, and fault messages are displayed on the screen to indicate the system's current status.	Substantially equivalent
Single Fault Tolerance	Automatic System Performance Monitoring in real-time with multiple fault tiers + visual supervision by surgeon via LED indicating system status. Examples include: - Redundant encoders on motorized axes - Velocity, acceleration,	Same	Searching redacted 510(k) for "single fault" of "fault" does not yield useful information. Moon Surgical does not know about their design in this regard other than the following: "Motor current limitation - applying relatively heavy weight on the ARM will cause	Substantially equivalent

ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Primary predicate Device)	MST – MEDICAL SURGERY TECHNOLOGIES LTD (Secondary predicate device)	COMPARISON
	current and torque limits Brakes engage if power is removed		the motors' currents to rise above a pre-defined threshold. As a response the system will electronically shutdown the motors and no motorized movement will be enabled."	
Back-up fault response	Brakes engage on motorized axis in the event of a fault state to prohibit any arm motion	Same	No information	Substantially equivalent
Maximum Applied Load	4.4 lbs tested.	Same	600 grams	Substantially equivalent
Compatible with	5mm and 10mm laparoscopes and laparoscopic instruments 5mm and 10mm laparoscopes for Scopilot	5mm and 10mm laparoscopes and laparoscopic instruments	5mm and 10mm laparoscopes	Substantially equivalent
Sterilization Method	Ethylene Oxide (EtO) – for coupling devices used to attach laparoscopic instruments	Same	Ethylene Oxide (EtO)	Substantially equivalent
Sterility barrier	Drape	Drape	Drape	Identical

Testing Performed

Testing described in this 510(k) consisted of verification of the Scopilot input requirements and product specifications. All requirements were validated. Design verification testing included the following:

- Payload Capacity
- Malformed Input
- Force Accuracy
- Drape Integrity
- Emergency Stop
- Hold Position Accuracy
- IFU Inspection
- Positioning Guidance & Collision Detection
- ScoPilot Motion Performance
- System Positioning Accuracy
- Bedside Joint Control Accuracy
- End to End Workflow
- Design Inspection
- System Setup
- System Latency
- Electro-Cautery Compatibility
- ScoPilot Latency
- ScoPilot End to End
- ScoPilot IFU Inspection
- System Endurance
- ScoPilot Vision Performance
- ScoPilot Malformed Input
- Cybersecurity
- Coupler Performance
- Electrical safety and electromagnetic compatibility (EMC)

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket

Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". Software testing included testing the software modifications made to implement the new ScoPilot features. This includes detection and tracking of specified instrument tips, generation of motion trajectories, safety limits and detection of malformed inputs at a video and frame level.

ScoPilot Validation testing

The ML model was trained and tuned through a K-fold cross-tuning process to optimize hyperparameters, until it reached our predefined performance requirements. An independent testing dataset containing videos was used to verify that the model performance (lower bound of the 95%CI for AP and AR) is compliant with our specification when using data including brands unseen during training/tuning.

Design validation testing included the following:

- Human factors testing
- Cadaver testing

Summary

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Maestro System has been shown to be substantially equivalent to the cited predicate devices.