



June 27, 2025

Moon Surgical
Marion Bruchet
Regulatory Affairs Manager
9 rue d'Enghien
Paris, 75010
France

Re: K250984
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: March 31, 2025
Received: March 31, 2025

Dear Marion Bruchet:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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

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

Digitally signed by Mark
Trumbore -S
Date: 2025.06.27 07:50:49
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Enclosure

Indications for Use

510(k) Number (if known)
K250984

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.

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Premarket Notification 510(k) Summary

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: K250984

Date Prepared: June 26th, 2025

Applicant Information:

Name: Moon Surgical
Address: 117 Quai de Valmy
75010 Paris France

Contact Person:

Marion Bruchet
mbruchet@moonsurgical.com
Mobile Number: +33670569899

Back-up Contact:

Michael A. Daniel
madaniel@clinregconsult.com

Device Information:

Device Trade Name: Maestro System
Common Name: Maestro System
Classification Name(s): Software Controlled Endoscope and Instrument Holder
Product Code/ Regulation: QZB 21 CFR 876.1500
Classification: Class 2

Predicate Device: Maestro System (K242323)

Maestro System 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 5G and WiFi capability to the previously cleared Maestro System (K242323). This modification is intended for data offload; only Telemetry and Event logs will be sent over 5G or WiFi. A PCCP is also implemented for the ScoPilot feature.



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 (Predicate Device)	COMPARISON
Device Name	Maestro System	Maestro System	N/A
510(k) Number	Not yet assigned	K242323	N/A
Product Code / Regulation	QZB / 876.1500 Software Controlled Endoscope and Instrument Holder	QZB / 876.1500 Software Controlled Endoscope and Instrument Holder	Identical
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	Identical
Intended Use / Indications for Use	The Maestro System is intended to hold and position laparoscopic Instruments during laparoscopic surgical procedures.	Same	Identical
System basic components	Two motorized Arms that hold and position the laparoscope and/or laparoscopic instruments Two stages, supporting and positioning the arms A Control Unit that controls the movements of the arms Instrument Coupling	Same	Identical



ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Predicate Device)	COMPARISON
	A User interface for system setup and feature selection		
Method of instrument attachment	Mechanical clamp around laparoscopic instrument and mechanical attachment to arm	Same	Identical
Mechanisms involved in physical positioning	Electro-mechanical jointed arms driven by internal motors that follow the physician movements.	Same	Identical
Method of control	Movement of the laparoscope is enabled only upon applied force to the instrument handle.	Same	Identical
Endoscope Movement	<u>Manual Control</u> Control algorithm applying motor current for instrument motion triggered by physician’s direct movement <u>Instrument Based Control</u> Image processing algorithms that enable the detection of known surgical tools within the displayed video image and when commanded by the surgeon, follow the movement of the chosen tool.	Same	Substantially equivalent – the PCCP in this submission intends to train the model on a new instrument class and on currently known classes (additional or currently known brands)
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	Identical
Single Fault Tolerance	Automatic System Performance Monitoring in real-time with multiple fault tiers + visual supervision by	Same	Identical



ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Predicate Device)	COMPARISON
	<p>surgeon via LED indicating system status.</p> <p>Examples include:</p> <ul style="list-style-type: none"> - Redundant encoders on motorized axes - Velocity, acceleration, current and torque limits <p>Brakes engage if power is removed</p>		
Back-up fault response	Brakes engage on motorized axis in the event of a fault state to prohibit any arm motion	Same	Identical
Data storage	Event logs and real-time Telemetry information are stored on the Not-Real-Time PC disk for offline use before being offloaded to the cloud through 5G or Wifi network	Event logs and real-time Telemetry information are stored on the Not-Real-Time PC disk for offline use	Substantially equivalent – the same data is stored but the connectivity feature allows to offload to the cloud through 5G or Wi-fi network
Maximum Applied Load	4.4 lbs tested.	Same	Identical
System dimensions:	<p>Height: 151-180 cm</p> <p>Width 68 cm</p> <p>Depth (min) 87-117 cm</p>	Same	Identical
System weight	290 kg (640 LBS)	322 kg (721 LBS)	Substantially equivalent – the change of weight is an ease-of-use improvement, it does not impact the performance or safety of the system
System OS	Linux based on Nvidia Holoscan Yocto v1.0.0	Linux based on Nvidia Holoscan Yocto v0.5.1	Substantially equivalent – the



ASPECT	MOON SURGICAL (Subject Device)	MOON SURGICAL (Predicate Device)	COMPARISON
	QNX 7.1.0	QNX 7.1.0	change of Linux OS version is to update its software components to more up-to-date versions. There is no user-facing change between the two Linux OS versions.
Compatible with	5mm and 10mm laparoscopes and laparoscopic instruments 5mm and 10mm laparoscopes for ScoPilot	Same	Identical
Sterilization Method	Ethylene Oxide (EtO) – for coupling devices used to attach laparoscopic instruments	Same	Identical
Sterility barrier	Drape	Same	Identical

SUMMARY OF NONCLINICAL/BENCH STUDIES

The following non-clinical test were leveraged to demonstrate safety and effectiveness for the subject device's indication for use.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with IEC 60601-1:2005+A1+A2 and IEC 60601-1-6:2010+A1+A2 for safety and the IEC 60601-1-2:2014+A1 for EMC. Wireless immunity and coexistence testing were also conducted on the device. The device complies with AIM 7351731 Rev. 3.00: 20201 for electromagnetic immunity and IEEE/ANSI C63.27:2021 for wireless coexistence.

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.

Performance Testing

Design verification testing included the following:

- Payload Capacity
- Malformed Input
- Force Accuracy
- Emergency Stop
- Hold Position Accuracy
- IFU Inspection
- Positioning Guidance & Collision Detection
- System Positioning Accuracy
- Bedside Joint Control Accuracy
- End to End Workflow
- Design Inspection
- System Setup
- System Latency
- Electro-Cautery Compatibility
- System Endurance
- Cybersecurity
- System Data Logging
- System Connectivity
- System Cloud Data
- OS
- ScoPilot Motion Performance
- ScoPilot Vision Performance

Design validation testing and usability validation were not performed since the modification is not user-facing, does not add or modify risks, and does not impact the clinical safety and performance of the Maestro System (K242323), nor the user interface or user tasks.

Predetermined Change Control Plan for ScoPilot

The detailed description of the planned modifications, testing methods, validation activities, performance requirements, and communication to users are summarized in the table below:



Planned modifications	Test Methods and Validation Activities	Communication to users, as needed
<p>Modification retraining the ML model with the addition of newly acquired data enables it to detect surgical instrument classes already claimed, and an increased variety of other brands in the video feed more accurately.</p>	<p>The verification and validation activities are identical to the previously cleared instrument classes with equivalent performance metrics as outlined in the Modification Protocol.</p>	<p>The labeling will be reviewed and updated as needed, in accordance with the authorized PCCP, to provide users with current information regarding the ScoPilot upgrade.</p> <p>Users will be notified of the ML model update, by receiving a release note and the new user manual, and by the intervention of a Moon employee to install the new software version</p>
<p>Modification adding surgical cautery hooks to the ML model class hooks as another surgical instrument class.</p>		

Summary

Based upon the Proposed Modifications outlined in the PCCP, 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 and does not raise questions of safety or effectiveness.