June 3, 2024

Moon Surgical
% Michael Daniel
Consultant
Daniel & Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

Re: K240598
Trade/Device Name: Maestro System (REF100)
Regulation Number: 21 CFR 878.4960
Regulation Name: Operating tables and accessories and operating chairs and accessories
Regulatory Class: Class I
Product Code: QZB
Dated: March 2, 2024
Received: March 4, 2024

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.

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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.06.03 14:50:58 -04'00'

Long Chen, 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)*

K240589

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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5. 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: K240589

Applicant Information:

Date Prepared: July 6, 2023
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):	Table, Operating-Room, AC-Powered
Product Code/ Regulation:	QZB 21 CFR 870.4960
Classification:	Class I

Predicate Device:

Maestro System (K221410)

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 design changes to the previously cleared Maestro System. The following modifications have been implemented to the Maestro System:

- System Positioning Guidance
- System Hold Status Indication
- Instrument Coupling
- System Setup
- Bedside Setup Joint Control

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 device.

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
Device Name	Maestro	Maestro	N/A
510(k) Number	K221410	Not yet assigned	N/A
Product Code / Regulation	FQO / 878.4960 Table Operating-room, AC-Powered.	FQO / 878.4960 Table Operating-room, AC-Powered.	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. Its major components consist of the Surgical Base, Surgical Arms, Control Unit, Instrument Coupling, and Control Station.	The Moon Surgical Maestro device is an electrically actuated device with movable components intended for laparoscopic surgical procedures to support and position laparoscopic instruments. Its major components consist of the Surgical Base, Surgical Arms, Control Unit, Instrument Coupling, and Control Station.	Identical
Intended Use / Indications for Use	The Maestro System is intended to hold and position laparoscopic Instruments during laparoscopic surgical procedures.	Same	Identical
Mechanism of Action (System Actuation / Positioning)	The Moon Maestro System utilizes DC motors to compensate for gravitational forces applied to laparoscopic instruments.	Same	Identical

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
	Software and hardware are designed to maintain instrument position. Surgeon control is achieved by grasping the handle of conventional laparoscopic tools and moving the tool to the desired position. Once surgeon hand force is removed, the Maestro system reverts to maintenance of the specified location including orientation.		
Endoscope Movement	Control algorithm applying motor current for instrument motion triggered by physician direct movement.	Same	Identical
Platform / Mechanism of stable attachment of arms	Jointed arms are attached to stages located on a portable base that can be locked in position. The bases are locked in position during system use.	Same	Identical
Cart Setup prior to procedure initiation	No positioning guidance	Sensors have been added to improve system positioning and setup prior to procedure initiation. These sensors monitor OR table position and distance as the user advances the system toward the OR table. The user always has the freedom to position the system where they want, but the guidance provides the recommended window of placement	Substantially equivalent with no new or different questions of safety or effectiveness.
System Setup	User-controlled powered x & z translation of the arms, and manual translation of the	User-selectable preset position for each specific clinical procedure to be	Substantially equivalent with no new or different

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
	shoulder roll via a toggle on the system console.	performed, chosen off a menu on the system console. Discrete manual control of these degrees of freedom always remains available to the user on the system console for fine adjustments via user-controlled powered x & z translation of the arms, and user-controlled powered translation of the shoulder roll	questions of safety or effectiveness.
Bedside Setup Control	Lack of complete control over the setup joints from the surgeon's bedside position. Adjusting x & z setup joints required interfacing with the non-sterile console on the system.	A control collar was added to each Maestro arm's forearm . Adjusting x, z and shoulder roll setup joints no longer requires interfacing with the non-sterile console. In all cases, if an instrument is attached during positioning adjustments, the system maintains the instrument's tip position during any setup joint motion.	Substantially equivalent with no new or different questions of safety or effectiveness.
Arm Proximity Indicator	No Arm Proximity Indicator	Sensors have been added to improve arm positioning by monitoring for objects within an established range. When an object enters that range, the system emits an audible chime, and provides a notification on the Console.	
Method of instrument attachment	Mechanical clamp around laparoscopic instrument and magnetic attachment to arm	Mechanical clamp around laparoscopic instrument and	Substantially equivalent with no new or different

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
		mechanical attachment to arm	questions of safety or effectiveness
Instrument Coupling	Self-orienting sterile couplers attached to the instrument's shaft. Two coupler sizes were used, 10 mm and 5 mm, to accommodate the most typical surgical instrument shaft calibers	A modified Coupler design maintains the same functionality and sizes (5 and 10 mm). Alignment and constraints are achieved through new mechanical methods on the modified coupler.	Substantially equivalent with no new or different questions of safety or effectiveness
Mechanisms involved in physical positioning	Electro-mechanical jointed arms driven by internal motors that follow the physician movements.	Same	Identical
Method of control	Direct manipulation of conventional laparoscopic instrument handles. Endoscope and Instrument positions are unlocked via surgeon applied force to laparoscope or instrument handles. This unlocking force is on the order of magnitude of what would be expected in holding or repositioning the endoscope or instruments themselves. The endoscope or instruments are repositioned as desired by the surgeon. Once the surgeon releases the instruments or scope the system maintains the new position with motor driven forces sufficient to compensate for gravity.	Same	Identical
System Hold Status Indicator	Two LED indicators on the system forearms are used to indicate transitions between	The three LED locations have been expanded and pushed further proximal on	Substantially equivalent with no new or different

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
	co-manipulation and hold states as they change between purple and blue, respectively	the device. LED indicators are present at the elbow and shoulder of the support arm. In addition to the visual indicators, the system now has light tactile feedback upon transition from co-manipulation to hold for information purposes to the user. The system provides short vibrations along the axis of the instrument, which the surgeon feels while holding the instrument.	questions of safety or effectiveness.
Alarm and Warning Condition Indicators	The Maestro has two primary LEDs for communication to the surgeon. These LEDs change colors and pulse to communicate system status. In the case of a critical system fault, the LEDs will change to red. The Maestro is also equipped with a touch screen graphical interface. This screen provides messages to the operating room staff regarding system state.	Same	Identical
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	Same	Identical

ASPECT	MOON SURGICAL (Predicate Device)	MOON SURGICAL (Subject Device)	COMPARISON
	- Velocity, acceleration, current and torque limits - Brakes engage if power is removed		
Back-up fault response	Brakes engage on motorized axis in the event of a fault state to prohibit any arm motion	Same	Identical
Maximum Applied Load	4.4 lbs tested.	Same	Identical
Sterilization Method	Steam - for coupling devices used to attach laparoscopic instruments	Ethylene Oxide (EtO) – for single use coupling devices used to attach laparoscopic instruments	Substantially equivalent with no new or different questions of safety or effectiveness
Sterility barrier	Drape	Same	Identical

Testing Performed

Design verification testing included the following:

- Payload capacity
- Single fault condition
- Force accuracy
- Drape integrity
- Hold position accuracy.
- Positioning guidance and collision detection
- System positioning accuracy
- Bedside joint control
- System end-to-end workflow
- Design inspection
- System setup
- System latency
- System cleaning
- LED status
- Emergency stop
- Coupler performance
- IFU inspection
- Software verification

- Electrical safety
- EMC

Design validation testing included the following:

- Cadaver testing
- Human factors testing

Testing described in this 510(k) consisted of verification of all system input requirements and product specifications. All clinical input requirements were validated.

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 device.