December 2, 2022

Moon Surgical
℅ Michael Daniel
President
Daniel & Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

Re: K221410
Trade/Device Name: Maestro Platform
Regulation Number: 21 CFR 878.4960
Regulation Name: Operating Tables And Accessories And Operating Chairs And Accessories
Regulatory Class: Class I
Product Code: FQO
Dated: November 2, 2022
Received: November 3, 2022

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 (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,

Jessica Carr -S

for Long Chen, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221410

Device Name
Maestro System

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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510(k) Summary (K221410)

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: K221410

Applicant Information:

Date Prepared:	November 28th, 2022
Name:	Moon Surgical
Address:	7/11 Blvd Haussmann 75009 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:	FQO 21 CFR 878.4960
Classification:	Class I

Predicate Device:

ENDEX Endoscopic Positioning System (K936308)

Subject Device Description

The Moon Maestro System 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.

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.

Table 1 - Comparison between subject and predicate device

ASPECT	ANDRONIC DEVICES LTD. (Predicate)	MOON SURGICAL (Subject Device)	COMPARISON
Device Name	ENDEX	Maestro	N/A
510(k) Number	K936308	K221410	N/A
Product Code / Regulation	FQO / 878.4960 Table Operating-room, AC-Powered	FQO / 878.4960 Table Operating-room, AC-Powered.	Previous "Operating table" related codes are now all Class I 510(k) exempt.
Brief Description	The ENDEX Endoscopic Positioning System is an electrically actuated, air or nitrogen-powered device with movable components intended for laparoscopic surgical procedures to support and position laparoscopic instruments. Its major components consist of the Endoscopic Positioner (consisting of the Positioning Arm and Table Module), Control Unit, Scope Driver (formerly called the Instrument Positioning Effector), Grasper Holder (formerly called the Instrument Holding Effector), Arm Release Button, Scope Driver Control Footswitch, Scope Driver Control Hand switch, and High-Pressure Hose.	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	Predicate is electrically actuated pneumatic and software driven mechanical system. The subject device is strictly electrically actuated and utilizes software to maintain instrument position by compensating for gravity.
Intended Use / Indications for Use	Intended to hold and position laparoscopes and laparoscopic instruments in laparoscopic cholecystectomies and advanced laparoscopic surgical procedures.	The Maestro System is intended to hold and position laparoscopes and laparoscopic instruments during laparoscopic surgical procedures.	Substantially Equivalent (SE)
Mechanism of Action (System Actuation / Positioning)	The ENDEX Endoscopic Positioner "remains locked when the gas source is applied and has a positioner unlock control button that permits the surgeon to easily unlock and reposition the device without compromising the sterility of the surgical field."	The Moon Maestro System utilizes DC motors to compensate for gravitational forces applied to laparoscopic instruments. Software and hardware are designed to maintain instrument position. Surgeon control is achieved by grasping the handle of conventional laparoscopic tools and moving the	The predicate has two (2) operating modes. One locks the instrument arm/holder in the location desired by surgeon and the second mode allows motor driven endoscope

ASPECT	ANDRONIC DEVICES LTD. (Predicate)	MOON SURGICAL (Subject Device)	COMPARISON
	The ENDEX Scope Driver is an electrically powered device for translating the position of laparoscopic surgical instruments. Both instruments and endoscope positions can be adjusted electromechanically via motor driven polymer "rollers" making contact with the endoscope or instrument shafts.	tool to the desired position. Once surgeon hand force is removed, the Maestro system reverts to maintenance of the specified location including orientation. Unlike the predicate, there is no motorized movement of instruments. Only maintenance of position.	or instrument positioning.
Platform / Mechanism of stable attachment of arms	Aluminum jointed arms are clamped to operating table rail or base via mechanical screw clamps.	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.	SE
Method of instrument attachment	Mechanical clamp	Mechanical clamp around laparoscopic instrument and magnetic attachment to arm	SE
Mechanisms involved in physical positioning	Jointed arms locked in place via nitrogen or air. The pneumatic lock and unlock states are controlled via electrical switches in either hand or foot switch locations. Endoscope and Instruments are held in place against gravity force by metallic jointed arms. The ENDEX Scope Driver is an electrically powered device for translating the position of laparoscopic surgical instruments. Both instruments and endoscope positions can be adjusted electromechanically via motor driven polymer "rollers" making contact with the endoscope or instrument shafts. Forward and backward motion is controlled by footswitch.	Electro-mechanical jointed arms driven by internal motors that follow the physician movements. Unlike the predicate, there is no motorized movement of instruments. Only maintenance of position.	SE – subject device is more sophisticated in design. However, fundamental function remains substantially equivalent in terms of intended use and functions related to positioning and holding an endoscope and instruments
Method of control	On/off switch for application of pneumatic locking mechanism. Joystick or foot switch control of laparoscope	Direct manipulation of conventional laparoscopic instrument handles. Endoscope and Instrument positions are unlocked via surgeon applied	SE – subject device is more sophisticated in design. However, fundamental function

ASPECT	ANDRONIC DEVICES LTD. (Predicate)	MOON SURGICAL (Subject Device)	COMPARISON
	or laparoscopic instrument movement. Fundamental control is achieved through electrical switch unlock or release of pneumatic pressure followed by surgeon movement of endoscope or instruments into desired location followed by electrical switch re-actuation of pneumatic lock.	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.	remains substantially equivalent in terms of intended use and functions related to positioning and holding an endoscope and instruments.
Alarm and Warning Condition Indicators	The Endex system has two user indicators: the low-pressure light and the scope movement tone. The low-pressure light illuminates when supply gas pressure falls below 100 psi. Recommended supply pressure necessary for optimal arm strength is 200 psi. The scope or instrument movement tone is activated whenever the driver is moving the scope or instrument. This movement is controlled via the footswitch. The volume is adjustable and may be turned off.	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.	SE – subject device is more sophisticated in design. However, fundamental function remains substantially equivalent in terms of intended use and functions related to positioning and holding an endoscope and instruments.
Single Fault Tolerance	Visual supervision by surgeon	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, current and torque limits - Brakes engage if power is removed	SE
Back-up fault response	None	Brakes engage on motorized axis in the event of a fault state to prohibit any arm motion	SE

ASPECT	ANDRONIC DEVICES LTD. (Predicate)	MOON SURGICAL (Subject Device)	COMPARISON
Maximum Applied Load	5 lbs "maximum force generated by Scope Driver"	4.4 lbs tested.	No exertion of force by subject device
Sterilization Method	Steam	Steam (for coupling devices used to attach laparoscopic instruments)	SE
Sterility barrier	Drape	Drape	SE

Performance Testing

Design validation testing included the following:

- Positional reach and trocar accommodation
- Payload capacity
- System cart stability
- Single fault condition
- Force measurement accuracy
- Brake hold
- Electrical insulation
- LED status
- Drape integrity
- Emergency stop
- Software validation
- Electrical safety
- EMC
- Sterilization validation
- Gravity compensation accuracy
- Coupler performance
- Cadaver testing
- Human factors testing

All testing had passed in accordance with the pre-specified success criteria, international standards or FDA guidances.

Conclusion

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.