October 28, 2022

CooperSurgical, Inc.
Yin Huang
Regulatory Affairs Specialist
95 Corporate Drive
Trumbull, CT 06611

Re: K223064
Trade/Device Name: ALLY II UPS™ (Uterine Positioning System)
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: September 28, 2022
Received: September 30, 2022

Dear Yin Huang:

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,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K223064

Device Name
ALLY II UPS™ (Uterine Positioning System)

Indications for Use *(Describe)*
The ALLY II UPS™ (Uterine Positioning System) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

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.

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510(k) Summary – K223064

ALLY II UPS™ (Uterine Positioning System)

I. Submitter Information

Company Name:	CooperSurgical Inc.
Company Address:	95 Corporate Drive Trumbull, CT 06611 Telephone: 203-601-5200
Contact Person:	Yin Huang Regulatory Affairs Specialist
Date Prepared:	October 27, 2022

II. Device Information:

Trade Name:	ALLY II UPS™ (Uterine Positioning System)
Common Name:	Uterine positioning system
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulation Number:	884.4530
Regulatory Class:	II
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

III. Predicate Device Information:

ALLY Uterine Positioning System™ (K141523), manufactured by CooperSurgical Inc.
The predicate device has not been subject to a design-related recall

IV. Device Description:

The ALLY II UPS™ (Uterine Positioning System) attaches to the operating room table and enables the bed-side assistant to readily mount, hold, and position the manipulator during laparoscopic surgical procedures. The ALLY II UPS enables access and provides the ability to maneuver and maintain the manipulator in a desired position. The ALLY II UPS consists of the ALLY II UPS and a manipulator adapter with built-in sterile drape, known as the adapter drape.

The CooperSurgical ALLY II UPS is a non-patient contacting, electromechanical device that consists of a single, multi-segmented, articulated arm. The ALLY II UPS can be attached to the standard operating room bed rail, and a separate, sterile, disposable Adapter Drape that is used to attach a uterine manipulator to the ALLY II UPS. When unlocked, the flexible arm allows the attached manipulator to be positioned by the user. The arm can then be locked in the desired position by releasing a foot pedal, activating a linear actuator that applies tension to an internal cable, drawing the segments together and thus locking the arm. The segmented design of the arm allows lateral/medial movement from a single point to position the uterine manipulator.

The purpose of this submission is to gain clearance for minor modifications made to the ALLY Uterine Positioning System to meet user needs and allow for user convenience. The overall functionality and interface of the ALLY II UPS for the user remains the same.

V. Indications for Use:

The ALLY II UPS™ (Uterine Positioning System) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

VI. Comparison of Technological Characteristics with the Predicate Device

A comparison of the intended use and technological characteristics of the subject and predicate device are included in the table below.

Attribute	Predicate ALLY Uterine Positioning System (UPS) - K141523	Subject ALLY II UPS™ (Uterine Positioning System)	Comparison
Principles of Operation	The ALLY II UPS™ (Uterine Positioning System) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.	The ALLY II UPS™ (Uterine Positioning System) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.	**Identical**
Sterilization	Non-sterile	Non-sterile	**Identical**
Range of motion	When the device is attached to the operating table bed rail: Anteverted hand position - The distal tip of the uterine manipulator attached to the device can reach the: • Anteverted hand position can manipulate to designated 6 points of extension Retroverted hand position – Not Applicable	When the device is attached to the operating table bed rail: Anteverted hand position - The distal tip of the uterine manipulator attached to the device can reach the: • Anteverted hand position can manipulate to designated 6 points of extension Retroverted hand position - Retroverted hand position is able to manipulate to designated 5 points of extension	**Different:** The subject device has greater Range of Motion than the predicate. The Range of Motion difference does not raise different questions of S&E.
Rotation angle of the Elbow	None – elbow is fixed at 50° toward sagittal plane of patient	Rotate 70° away from the sagittal plane of patient	**Different:** The subject device has greater Range of Motion than the predicate. The Elbow rotation difference does not raise different questions of S&E

Material(s) of the arm LINKs	303 stainless Steel	17-4 stainless steel	**Different:** This modification allows for a longer useful life of the Flexible Arm for the subject device than the predicate The material change does not raise different questions of S&E
PEEK Inserts in the LINKs and Elbow	No protective inserts over actuator cable	Additional inserts to provide a protective barrier for the cable	**Different:** This modification allows for a longer useful life of the Flexible Arm for the subject device than the predicate. The PEEK insert in the LINKs does not raise different questions of S&E
Foot pedal connection to device	Hard wired to device - undetachable	Connector can be detachable	**Different:** The subject device provides more convenience for users than the predicate by allowing ease of mobility and packing of the device in moving the unit around the hospital. The detachable connection does not raise different questions of S&E
Grounding Post	None	Attached to bottom of device as a built-in feature for grounding the device	**Different:** The Grounding Post is added as an additional grounding option for hospitals when they have concerns over electrical grounding within the hospital setting. The Grounding Post does not raise different questions of S&E
Handle	Flat plate with finger holding	Whole hand handle	**Different:** This modification was made as an ergonomic change to provide more user convenience.

The subject ALLY II UPS has the same Intended Use, fundamental scientific technology, and similar materials as the predicate device. The subject device has an identical principle of operation and similar design to the predicate device.

The minor design changes for user convenience consist of:

1) Improvement to the range of motion of the flexible arm to give users more flexibility in positioning uterine manipulators during gynecological laparoscopic surgical procedures.
2) Minor modifications to the design features of the flexible arm to aid in flexibility, durability, and cleaning of the device.
3) Addition of a detachable foot pedal connection where the predicate device was hard wired into the unit.

The changes in technological characteristics do not raise different questions of safety and effectiveness.

VII. Performance Data

The support the proposed modifications to the subject device, design control activities and a risk analysis (depicting device change, risk associated, verification method, acceptance criteria and summary of results) was performed. The ALLY II UPS was tested to identified verification and validation activities including tests comparing the subject device to the predicate ALLY UPS – K141523.

- Durability (Useful Life) testing
- Holding force testing
- Range of motion testing
- Link Soak testing
- Foot Pedal Cable Retention Justification

The device is compliant with the following standards:

IEC 60601-1: 2005+AMD1:2012+AMD2:2020 CSV Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance

The subject ALLY II UPS met the pre-determined acceptance criteria for each intended output. Therefore, design verification testing determined that the subject ALLY II UPS is substantially equivalent to the identified predicate device.

VIII. Conclusion

The results of the testing described above demonstrate that the ALLY II UPS™ (Uterine Positioning System) is as safe and effective as the predicate device and supports a determination of substantial equivalence.