December 7, 2022

US Medical Innovations, LLC
% Stuart Goldman
Senior Regulatory Consulant
Emergo Global Consulting, LLC
2500 Bee Cave Rd, Bldg 1, Suite 300
Austin, Texas 78746

Re: K212736
Trade/Device Name: Canady Flex RoboWrist
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, GEI

Dear Stuart Goldman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 11/22/2022. Specifically, FDA is updating this SE Letter for a typo in the contact name on Page 2 as an administrative correction (Michael Siano should be replaced by Stuart Goldman).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. Long Chen, OHT4: Office of Surgical and Infection Control Devices, Long.Chen@fda.hhs.gov, 301-796-6389.

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

11/22/2022

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Trade/Device Name: Canady Flex RoboWrist
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GEI
Dated: October 20, 2022
Received: October 24, 2022

Dear Stuart Goldman:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212736

Device Name
Canady Flex RoboWrist™

Indications for Use *(Describe)*
The Canady Flex RoboWrist is intended for grasping, mobilization, dissection, transection, suturing, and/or electrocautery of tissue under direct and endoscopic visualization.

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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Canady Flex RoboWrist™

1. Submission Sponsor

US Medical Innovations, LLC
6930 Carroll Avenue, Suite 1000
Takoma Park, MD 20912-4467
United States
Contact: Dr. Jerome Canady
Title: CEO
(301) 270-0147

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com
Contact: Stuart R. Goldman
Title: Senior Regulatory Consultant
512.327.9997

3. Date Prepared

November 22, 2022

4. Device Identification

Trade/Proprietary Name:	Canady Flex RoboWrist™
Common/Usual Name:	Endoscopic Instrument
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	GCJ, GEI
Class:	Class II
Classification Panel:	Gastroenterology/Urology

5. Legally Marketed Predicate and Reference Devices

Predicate Device:
Novare Surgical Systems, Inc. – RealHand High Dexterity Instruments (K072715)
Reference Devices:
Covidien, LLC – iDrive System (K102325)
Covidien, LP – SILS™ (K091869)

6. Indication for Use Statement

The Canady Flex RoboWrist is intended for grasping, mobilization, dissection, transection, suturing, and/or electrocautery of tissue under direct and endoscopic visualization.

7. Device Description

The Canady Flex RoboWrist is a motorized, hand-held laparoscopic surgery instrument available with hook, scissors, or needle holder end-effectors. The device includes a connector for an electrosurgical generator, which allows the option of using the mono scissors or hook for electrosurgery. The Canady Flex RoboWrist primarily intended for dissection, transection, and/or suturing of tissue under direct and endoscopic visualization in minimally invasive surgical procedures for interventions such as laparoscopic (urologic, gynecologic) or thoracic surgeries.

The Canady Flex RoboWrist is composed of an instrument (with end-effectors) and a control unit, which provides power to the instrument. Three models of instruments are available: needle-holder, monopolar hook and monopolar scissors. An electrical cable is provided to connect the instrument to the control unit. It is also provided with a sterilization tray.

8. Substantial Equivalence Discussion

The following table compares the Canady Flex RoboWrist to the predicate device forming the basis for the determination of substantial equivalence.

	Subject Device (K212736)	**Predicate Device (K072715)**	**Comparison**
Tradename	Canady Flex RoboWrist™	RealHand™ High Dexterity Instruments	Different
Manufacturer	US Medical Innovations, LLC	Novare Surgical Systems, Inc.	Different
Class	II	II	Same
Product Code	GCJ	GCJ	Same
Regulation Number	876.1500	876.1500	Same
Indications for Use	The Canady Flex RoboWrist is intended for grasping, mobilization, dissection, transection, suturing, and/or electrocautery of tissue under direct and endoscopic visualization.	The RealHand High Dexterity (HID) instruments are intended for grasping, mobilization, dissection, transection, suturing, and/or electrocautery of tissue under direct and endoscopic visualization.	Same
Conditions of Use	Rx Only; Clinical environment	Rx Only; Clinical environment	Same
Principle of Operation	The Canady Flex RoboWrist consists of an articulated motorized needle holder, scissors and hook that is designed to allow access to difficult areas to reach in the abdomen. The devic includes motorization of two movements for accessing surgical sites and laparoscopic suturing. The user manages these movements using the	RealHand™ High Dexterity Instruments consist of a handle, jaws, and a shaft which includes distal and proximal articulating sections. The instrument jaws are activated by compressing and releasing the handle. The handle can include a ratchet and ratchet release which allow the instrument jaws to be locked in place, a rotation control wheel and articulation lock.	Different

	control ring over the instrument.		
Design characteristics	Instrument composed of a hand-held handle, a shaft and an end effector that can be jaws/ scissors/hook. Instrument is articulated (shaft) and can rotate (distal section of the shaft) and is lockable.	Instrument composed of a hand-held handle, a shaft and an end effector that can be jaws/scissors/hook/dissector. Instrument is articulated (shaft), can rotate (distal section of the shaft) and is lockable.	Similar
Power Source	Electrical energy	Manual	Different
Sterility	User sterilized	Sterile	Similar
Sterilization Method	Moist Heat	Irradiation	Different
Single Use/reusable	Reusable	Single use	Different
Performance	Product testing was conducted to evaluate conformance to product specification. Testing included manipulating, cutting and suturing of tissue.	Product testing was conducted to evaluate conformance to product specification. Testing included grasping, manipulating, cutting and suturing of tissue.	Different

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the Canady Flex RoboWrist and to show substantial equivalence to the predicate device, the following non-clinical tests were performed. Results confirm that the design inputs and performance specifications for the device are met. The device passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5
- Sensitization testing per ISO 10993-10
- Intracutaneous reactivity testing per ISO 10993-10
- Acute systemic toxicity testing per ISO 10993-11
- Material-mediated pyrogenicity testing per ISO 10993-11
- Electrical safety testing per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-1-2
- Cleaning and sterilization validations per ISO 17665-1
- Human Factors/Usability testing per IEC 62366
- Functionality testing including manipulating, cutting and suturing

10. Statement of Substantial Equivalence

The subject device has the same indications for use as the predicate device. Differences in the technological characteristics have been evaluated through appropriate safety and performance testing, which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, Canady Flex RoboWrist has been determined to be substantially equivalent to RealHand High Dexterity (HD) Instrument (the predicate device).