



11/22/2022

US Medical Innovations, LLC  
% Stuart Goldman  
Senior Regulatory Consultant  
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  
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](mailto: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

## Indications for Use

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.

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# 510(k) Summary

## Canady Flex RoboWrist™

### 1. Submission Sponsor

US Medical Innovations, LLC  
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United States  
Contact: Dr. Jerome Canady  
Title: CEO  
(301) 270-0147

### 2. Submission Correspondent

Emergo Global Consulting, LLC  
2500 Bee Cave Road  
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Austin, TX 78746  
Office Phone: (512) 327-9997  
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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.

	<b>Subject Device (K212736)</b>	<b>Predicate Device (K072715)</b>	<b>Comparison</b>
<b>Tradename</b>	Canady Flex RoboWrist™	RealHand™ High Dexterity Instruments	Different
<b>Manufacturer</b>	US Medical Innovations, LLC	Novare Surgical Systems, Inc.	Different
<b>Class</b>	II	II	Same
<b>Product Code</b>	G CJ	G CJ	Same
<b>Regulation Number</b>	876.1500	876.1500	Same
<b>Indications for Use</b>	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
<b>Conditions of Use</b>	Rx Only; Clinical environment	Rx Only; Clinical environment	Same
<b>Principle of Operation</b>	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 device 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.		
<b>Design characteristics</b>	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
<b>Power Source</b>	Electrical energy	Manual	Different
<b>Sterility</b>	User sterilized	Sterile	Similar
<b>Sterilization Method</b>	Moist Heat	Irradiation	Different
<b>Single Use/reusable</b>	Reusable	Single use	Different
<b>Performance</b>	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).