December 22, 2020

AKTORmed GmbH
% Martin Dumberger
Managing Director
Micro-Epsilon America
8120 Browneigh Road
Raleigh, North Carolina 27617

Re: K200473
Trade/Device Name: SoloAsisst II, Voice Control
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: February 14, 2020
Received: February 26, 2020

Dear Martin Dumberger:

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,

Je Hi An, 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)*

K200473

Device Name
SOLOASSIST II

Indications for Use *(Describe)*

The intended use of the SOLOASSIST II is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.

The SOLOASSIST II is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, SOLOASSIST II is used, are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement.

The users of the SOLOASSIST II are general surgeons, gynecologists, cardiac surgeon, thoracic surgeon and urologists.

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 for SOLOASSIST II

The 510(k) summary information is being submitted in accordance with the requirements of the Code of Federal Regulations Title 21 section 807.92.

1. Prepared by

Name and date 510(k) Summary was prepared	Author name: Andreas Mohr Date created: 2020-Jan-07

2. 510 (k) Submitter

Manufacturer / 510(k) Submitter (Company Name, Address, Web)	AKTORmed GmbH Borsigstraße 13 D-93092 Barbing Germany http://aktormed.info/en/homepage
Contact Person for 510 (k) (Name, Title, Address, Phone & Fax Number, Email)	Andreas Mohr M.Sc. Borsigstraße 13 D-93092 Barbing Germany Tel: +49 9401 9320 150 Fax: +49 9401 9320 115 andreas.mohr@aktormed.com

3. New Device

Device Trade Name & Model Number(s) (The trade name is the name under which the device will be marketed)	SOLOASSIST II – Model Number: 141364 Voice Control – Model Number: 171894
Device Common or Usual Name (is the name of the device as it is commonly known e.g., syringe, hip implant.)	Endoscope Holder for Optimal Positioning
Device Medical specialty panels and Regulation Part Number (such as Anesthesiology 21CFR868, Cardiovascular Part 21CFR870, Chemistry 21CFR862, Dental 21CFR872…)	Gastroenterology-Urology 21 CFR 876
Device Regulation Number (such as 21CFR 868.1075 ..)	21 CFR 876.1500
Device Regulation Name (such as Argon gas analyzer…)	Endoscope and accessories
Device Classification Product Code (3 character unique product identifier)	NAY
Device Class (i.e., whether it is unclassified or a class I, II, or III device)	Class II

4. Predicate Device

(to which substantial equivalence is being claimed to)

Primary Predicate Device

Manufacturer / 510(k)Submitter (Company Name)	AKTORmed GmbH
Device Trade Name & Model Number(s) (The trade name is the name under which the device will be marketed)	SOLOASSIST II – Model Number: 141364
Device Regulation Number (such as 21CFR 868.1075 ..)	21 CFR 876.1500
Device Classification Product Code (3 character unique product identifier)	NAY
Device Class (i.e., whether it is unclassified or a class I, II, or III device)	Class II
Predicate Device 510(k) Number	K171947

Reference Device

Manufacturer / 510(k)Submitter (Company Name)	COMPUTER MOTION, INC.
Device Trade Name & Model Number(s) (The trade name is the name under which the device will be marketed)	AESOP 3000 System
Device Regulation Number (such as 21CFR 868.1075 ..)	21 CFR 876.1500
Device Classification Product Code (3 character unique product identifier)	GCJ
Device Class (i.e., whether it is unclassified or a class I, II, or III device)	Class II
Reference Device 510(k) Number	K972699

5. Description of the Device

Device Characteristics

SOLOASSIST

- Weight: 11,5kg
- Dimensions: 1153 x 401 x 270mm
- Safe working load: 1kg
- 3 motorized axes of the arm system
- Software based movement control of the arm system
- Controlled by JOYSTICK or VOICE CONTROL
- Quick-fastener
- Sterilization method: steam pressure sterilization (UNIVERSAL JOINT, JOYSTICK, ENDOSCOPE CLAMP, TENSION SLEEVE)

VOICE CONTROL

- Additional accessory (Input device) for the SOLOASSIST II to control the positioning of the arm system
- Weight: 4kg

- Dimensions: 80 x 350 x 250 mm

Environment of Use

- healthcare facility/hospital:
  - Operating room / operation table

Brief Written Description of the Device:

The SOLOASSIST II allows the user to hold and control the movements of a rigid endoscope by using a JOYSTICK, manually by pushing the release button on the Control Panel that is located on the SOLOASSIST II or using the VOICE CONTROL.

The JOYSTICK or the VOICE CONTROL is linked to related connection of the SOLOASSIST II by wire. The JOYSTICK is mounted on the surgical instrument of the surgeon. The movement will be controlled by three motorized axes inside the SOLOASSIST II. The SOLOASSIST II simulates an arm working in several degrees of freedom. The Control Panel of the SOLOASSIST II has 2 buttons and 5 indications. One button is used to set the TROCAR POINT and the other button is used to move the SOLOASSIST manually by pushing the button while moving the arm.

The TENSION SLEEVE and the ENDOSCOPE CLAMP are loosely screwed together. The combination of TENSION SLEEVE and ENDOSCOPE CLAMP are slide over the endoscope and the tension sleeve is tightened so the endoscope can't move out but still can turn. It is important to use the right TENSION SLEEVE for the right diameter of the endoscope. On the rigid endoscope normally there is a camera linked that sends a video to a monitor. Endoscope and camera as well as the monitor are not part of the SOLOASSIST II.

The starting point of the movement for an operation will be saved as the TROCAR POINT. The UNIVERSAL JOINT has to be mounted on the SOLOASSIST II. A mounted UNIVERSAL JOINT can be removed by using the release slider. To define the Trocar point the UNIVERSAL JOINT has a small tracer pin. The tracer pin is placed near the body opening for the endoscope. The TROCAR POINT has to be saved by pushing the button on the control panel of the SOLOASSIST II.

The ENDOSCOPE CLAMP (together with TENSION SLEEVE and Endoscope) is mounted on the UNIVERSAL JOINT, so the SOLOASSIST II is ready for operation.

Based on the trocar point and the desired view of the image, the software of the device calculates the required individual movements of the axes in order to achieve the desired total movement. For example by pushing the left button on the JOYSTICK the image on the monitor moves left, while the SOLOASSIST II is moving to produce the desired view. By pushing the buttons on the JOYSTICK it is possible to move the image on the monitor to the left, right, up, down, zoom in and zoom out.

Additionally it is possible to move the arm of the SOLOASSIST II without the use of the JOYSTICK. Therefore the user has to hold the control panel on the SOLOASSIST II and push the unlocking button (release button) while moving the arm system.

Additionally it is possible to move the arm of the SOLOASSIST II with the use of the VOICE CONTROL. Therefore the user has to put the headset on his head that is connected to the VOICE CONTROL by a Bluetooth-Dongle. The VOICE CONTROL is activated by using the hotword “SOLO”. The SOLOASSIST II moves by using predefined Movement Commands.

To allow the surgeon to convert to an open surgery in case of an emergency, the SOLOASSIST II can be completely mounted or removed by a quick fastener.

Key Performance Specifications/Characteristics of the Device

Stable fixation of an endoscope: The system holds an endoscope in a fixed position, which was adjusted by the user. This must also be assured when power is lost.

Enabling the repositioning of an endoscope: The system enables the user (surgeon) to reposition the endoscope by use of a JOYSTICK, VOICE CONTROL or manually. In case of power loss or other failures it is acceptable that this function is not available.

Manual repositioning of the system arm: The system enables the user (surgeon) to reposition the endoscope by pushing a button. In case of power loss or other failures it is acceptable that this function is not available.

6. Intended Use and Indication for Use

6.1. Intended Use

The SOLOASSIST II allows the user (surgeon) to control movements of a rigid endoscope directly by using the JOYSTICK or the VOICE CONTROL. The SOLOASSIST II is intended for use in minimally invasive abdominal surgery, thoracic surgery, urology surgery or gynecology surgery where a rigid endoscope is intended for use. The SOLOASSIST II gives the user the advantage of an image without jerking.

6.2. Indication for Use

The intended use of the SOLOASSIST II is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.

The SOLOASSIST II is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, SOLOASSIST II is used, are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement.

The users of the SOLOASSIST II are general surgeons, gynecologists, cardiac surgeon, thoracic surgeon and urologists.

6.3. Comparison to Predicate Device

The AKTORmed SOLOASSIST II is substantially equivalent in intended use and technology to the predicate device, SOLOASSIST II (K171947).

7. Comparison of Technological Characteristics with the Predicate Device

Holding and controlling the movement of a rigid endoscope by motorized axes is the technological principle for the SOLOASSIST II and the predicate devices. All devices are used for minimally invasive interventions with a software based assistance system. At a high level, the subject and predicate devices are based on the following same technological elements

- Use of motorized axes
- Same number of axes
- Use of a sterile drape to cover the device
- Use of input device to control the system
- Possibility to move the system manually
- Use of a power supply
- Same intended use

The following technological differences exist between the subject and predicate devices:

- VOICE CONTROL as input device
- The VOICE CONTROL is not integrated into the arm system
- Use of a VOICE CONTROL to transfer voice commands to movement of the SOLOASSIST II
- Use Voice Commands to move the system
- Separate software for the VOICE CONTROL
- Use of a Bluetooth Headset

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

8.1. Summary Non-Clinical Performance Data

8.1.1. Biocompatibility testing

The biocompatibility evaluation was conducted according to Directive 93/42/EEC, 90/385/EEC, DIN EN ISO/IEC 17025: 2005 (DAkkS D-PL-13392-01-00 accredited, ZLG-AP-311.10.26 recognized), and Good Laboratory Practices (GLP).

Following tests were conducted:

Cytotoxicity, L 929-Proliferation
EN ISO 10993-5, -12, LM P 4-06, LM SOP 4-06-01
Chemical analysis (characterization of organic leachables/extractables)
EN ISO 10993-1, -12, -18, LM P8-01, LM SOP 8-01-01

8.1.2. Electrical safety and electromagnetic compatibility (EMC)

The SOLOASSIST II complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC. They system also complies with IEC 60601-1-4 standard, IEC 60601-1-6 and IEC 60601-2-18.

For the VOICE CONTROL additional testing was performed for electrical safety and EMC testing. The VOICE CONTROL complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

8.1.3. Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "**Moderate**" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.
The SOLOASSIST II complies with the IEC 62304.

Additional Software verification and validation testing were performed and documented for the VOICE CONTROL. The software for this device was considered as a "**Major**" level of concern.
The VOICE CONTROL complies with the IEC 62304.

8.1.4. Mechanical, acoustic and bench testing

Mechanical, acoustic and bench testing were conducted.

Following tests were conducted:

- **Quick release connector and angle joint:**
  In this test the tilting of the SOLOASSIST II mounted on rails was tested (0°, 45°, 90°); also the engage of the angle joint of the SOLOASSIST II was tested according to functionality
- **Temperature test:**
  Testing the use of the device for its temperature range for use and testing the status of the device for its storage temperature range
- **Force test:**
  Testing the forces that are needed to move the arm system while in release status
- **Lifetime test:**
  35.000 movements in x-direction, 55.000 movements in y-direction, 35.000 movements in z-direction (movement length 30cm)
  Motor lifetime for at least 1000h (500h with cycle movement with radius 15cm and 28cm)
- **Testing moving after fixation:**
  - Shifting after manual positioning with 1kg load; 3 turns; averaged measurement 2,93mm
  - Falling speed after 2 hours: max. 0,0024mm / min
- **Tensile stress:**
  (Mechanic according to EN 60601-1:2016; Chapter 9.8.2): Examination weight 8,1kg (8x normal load)

- **Sound test:**
  (Mechanic according to EN 60601-1:2006, Chapter 9.6.2.1): 64,0 dBA (pushing release button); 60,2 dBA (during active operation and 1kg load)
- **Shock resistance:**
  (Mechanic according to EN 60601-1:2006, Chapter 15.3.2): continuous force of 240N for 5s (contact with surfaces by a 30mm diameter circular area)
- **Impact resistance:**
  (Mechanic according to EN 60601-1:2006; Chapter 15.3.3): Steel ball, weight 500g; Height of steel ball: 1,3m
- **Drop resistance:**
  (Mechanic according to EN 60601-1:2006, Chapter 15.3.4.2): SOLOASSIST II is hold over a wooden plate (d = 50mm +/- 5mm) in a height of 3cm. Dropped down 3 times out of each start situation that the SOLOASSIST II can be during the intended use.
- **Tightening test:**
  (Mechanic according to EN 60601-1:2006, Chapter 15.4.6.1): Turning star know clock and anti-clockwise ill stop and hold the position for 2s with a force of 4Nm. Repeated 10 times.
- **Functional Test Headset:**
  Testing the functionality of the Headset and the interaction with the VOICE CONTROL.
- **Functional Test Movement VOICE CONTROL:**
  Testing the Movement of the VOICE COMMANDS of the VOICE CONTROL. The Movement of the VOICE CONTROL is time based, not distance based.
- **Functional Test Bluetooth Reach:**
  Testing the Reach of the Bluetooth-Signal for the VOICE CONTROL. Following distances were tested: 5m, 10m, 15m, 20m and 25m.
- **Functional Test Voice Commands:**
  Testing all available VOICE COMMANDS for the VOICE CONTROL.

8.1.5. Animal Study

No animal study were conducted

8.1.6. Cybersecurity risk assessment

Cybersecurity risk assessment was conducted based on FDA guideline “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” for the SOLOASSIST II and VOICE CONTROL

8.1.7. Wireless risk assessment

Wireless risk assessment was conducted for the SOLOASSIST II and VOICE CONTROL

8.1.8. Sterilization

The Sterilization tests were conducted according to Directive 93/42/EEC, 90/385/EEC, DIN EN ISO/IEC 17025: 2005 (DAkkS D-PL-13392-01-00 accredited, ZLG-AP-311.10.26 recognized), and Good Laboratory Practices (GLP).

Following tests were already conducted:

- Microbiological efficiency control of steam sterilization, fractionated vacuum cycle / dynamic-air-removal cycle, product group sterilizable arm components
  EN ISO 17664, EN ISO 17665-1 (overkill method, partial cycle), ANSI/AAMI ST79, ANSI/AAMI ST81, ANSI/AAMI TIR12, ASTM E 1766 mod., EN 556-1, ANSI/AAMI ST67, KRINKO/RKI/BfArM guideline, LM P 2-11-04, LM SOP 2-11-04

- Microbiological efficiency control of the automated cleaning and disinfection, product group sterilizable arm components
  EN ISO 17664, ANSI/AAMI ST81, ANSI/AAMI TIR12 mod., AAMI TIR 30 mod., ASTM E 2314 mod., ASTM E 1837 mod., KRINKO/RKI/BfArM guideline, LM SOP 2-11-01

- Efficiency control for cleaning (optimized protein test) during automated cleaning/Disinfection, product group sterilizable arm components
  EN ISO 17664, ANSI/AAMI ST81, ANSI/AAMI TIR 12 mod., AAMI TIR 30, ASTM E 2314 mod. , KRINKI/RKI/BfArM guideline, FDA guidance, LM SOP 2-11-01

- Microbiological efficiency control of the manual cleaning and disinfection, product group sterilizable arm components
  EN ISO 17664, ANSI/AAMI ST81, ANSI/AAMI TIR12 mod., AAMI TIR 30 mod., ASTM E 2314 mod., ASTM E 1837 mod., KRINKO/RKI/BfArM guideline, LM SOP 2-11-02

- Efficiency control for manual cleaning (optimized protein test), product group sterilizable arm components
  EN ISO 17664, ANSI/AAMI ST81, ANSI/AAMI TIR 12 mod., AAMI TIR 30, ASTM E 2314 mod. , KRINKI/RKI/BfArM guideline, FDA guidance, LM SOP 2-11-01

- Efficiency control of the cleaning (TOC method) during automated cleaning / disinfection, product group sterilizable arm components
  EN ISO 17664, ANSI/AAMI/ISO 17664, ANSI/AAMI TIR12 mod., AAMI TIR 30, ASTM E 2314 mod, KRINKO/RKI/BfArM guideline, RDS 007, FDA guidance, LM SOP 2-11-01

8.1.9. Human Factor Testing

Human Factor Testing for the SOLOASSIST II was conducted according to FDA guideline “Applying Human Factors and Usability Engineering to Medical Devices” (issued on February 3, 2016)
Human factor test has been conducted for the SOLOASSIST II. There has been 15 operations conducted. The test was performed successfully. No unexpected device related events or patient related adverse events occurred during the Human Factor Testing.

Additional Human Factor Testing was conducted for the VOICE CONTROL. There has been 15 operations conducted. The test was performed successfully. No unexpected device related events or patient related adverse events occurred during the Human Factor Testing.

8.1.10. Packaging

Package drop test was conducted for the SOLOASSIST II and its trolley according to ISTA 1A. SOLOASSIST II and trolley have been packages in wooden box with filling materials. Drop height for mass 45 to 68kg was set to 200mm. All surfaces and relevant edges as well as a corner was tested. No damage of the SOLOASSIST II occurred.

Package drop test was conducted for the VOICE CONTROL according to ISTA 1A. VOICE CONTROL has been packaged in cardboard with filling materials. Drop height for mass less than 10kg was set to 760mm. All surfaces and relevant edges as well as a corner was tested. No damage of the VOICE CONTROL occurred.

8.2. Summary Clinical Performance Data

No Clinical testing were conducted.

8.3. Conclusion Performance Data

Based on the nonclinical performance data, we conclude that the SOLOASSIST II is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.