August 8, 2024

AKTORmed GmbH
Hanna Kafurke
Regulatory Affairs and Quality Manager
Neugablonzer Strasse 13
Neutraubling, BY 93073
Germany

Re: K233312
Trade/Device Name: SOLOASSIST IID / DEXTER ENDOSCOPE ARM (212499); ARTip solo (202426) + ARTip solo voice (202445); SOLOASSIST II (141364) + VOICE CONTROL (171894
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: QZB,
Dated: July 26, 2024
Received: July 26, 2024

Dear Hanna Kafurke:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.08.08 16:27:57 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233312

Device Name

SOLOASSIST IID / DEXTER ENDOSCOPE ARM (212499);
ARTip solo (202426) + ARTip solo voice (202445);
SOLOASSIST II (141364) + VOICE CONTROL (171894)

Indications for Use *(Describe)*

SOLOASSIST II
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 surgeons, thoracic surgeons and urologists.

DEXTER ENDOSCOPE ARM

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

The DEXTER ENDOSCOPE ARM is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons and urologists.

ARTip solo

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

The ARTip solo is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, ARTip solo 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 ARTip solo are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons 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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00	Erstellung / *created*	HK	03.11.2023
01	- „cleared“ instead of „approved“ - Chapter 8 extended	HK	07.11.2023
02	Update technological comparison and product code	HK	30.07.2024

510(k) Summary

Inhaltsverzeichnis / contents

1. Contact Details

21 CFR 807.92(a)(1)

Applicant Name	AKTORmed GmbH
Applicant Address	Neugablonzer Strasse 13, Neutraubling, BY, 93073, Germany
Applicant Contact Telephone	+49 9401 9320 150
Applicant Contact	Mrs. Hanna Kafurke
Applicant Contact Email	Hanna.kafurke@aktormed.com

2. Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SOLOASSIST IID / DEXTER ENDOSCOPE ARM (212499); ARTip solo (202426); ARTip solo voice (202445); SOLOASSIST II (141364); VOICE CONTROL (171894)
Common Name	Endoscope and accessories
Classification Name	Software Controlled Endoscope And Instrument Holder
Regulation Number	876.1500
Product Code	QZB

3. Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	K200473
Predicate Trade Name (Primary Predicate is listed first)	Soloassist II, Voice control
Product Code	NAY

4. Device Description Summary

21 CFR 807.92(a)(4)

DEXTER ENDOSCOPE ARM and ARTip solo + ARTip solo voice are based on the same concept as the already cleared SOLOASSIST II + Voice Control (K200473) and differ only in minor details. All 3 robotic arm systems emulate an arm operating in multiple degrees of freedom. The intended use of the three robotic arm systems is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope. The surgeon can control the arm with either a joystick, voice control, or by pressing a button on the distal end of the arm. Movement is controlled by 3 motorized axes. The endoscopic camera is registered in the TROCAR POINT, which serves as the pivot point. Starting from this zero point, the device independently calculates the required individual movements of the axes to achieve the desired overall movement. The system offers a wide range of motion, allowing a 360° panoramic view with the endoscope tilted up to 90° from the vertical. Despite their wide range of motion, all arms are lightweight and compact and are attached directly to the operating table with a quick-release clamp. Only a STERILE COVER is required for safe use.

The ARTip solo is functionally identical to the already cleared SOLOASSIST II (K200473), but differs only in the color and inscription of the covers and the visual design of the control panel on the arm.
The ARTip solo can also be controlled with the ARTip solo voice. This is also identical to the already cleared VOICE CONTROL (K200473) except for the color and inscription. The ARTip solo is not compatible with the VOICE CONTROL (K200473).

In addition, the ARTip solo can also be controlled with a joystick. It can only be controlled with the JOYSTICK-LH-IIA or JOYSTICK-RH-IIA, which are specially made for the ARTip solo and are only compatible with it.

DEXTER ENDOSCOPE ARM is the trade name of the SOLOASSIST IID, which was developed within the SOLOASSIST II. The special feature of the DEXTER ENDSCOPE ARM is that it provides an interface to a customer-specific device and can be controlled by it.
The arm can also be controlled by the JOYSTICK LH and JOYSTICK RH.
The SOLOASSIST IID has its own CANTILEVER, JOINT, PROBE PIN and ENDOSCOPE CLAMP, which in combination with a tension sleeve hold the endoscope.

5. Intended use/Indications for Use

21 CFR 807.92(a)(5)

SOLOASSIST II

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 surgeons, thoracic surgeons and urologists.

DEXTER ENDOSCOPE ARM

The intended use of the DEXTER ENDOSCOPE ARM is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.
The DEXTER ENDOSCOPE ARM is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons and urologists.

ARTip solo

The intended use of the ARTip solo is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.
The ARTip solo is indicated for use in minimally invasive interventions where a rigid laparoscope / endoscope is indicated for use. Surgeries, ARTip solo 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 ARTip solo are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons and urologists.

6. Indications for Use Comparison

21 CFR 807.92(a)(5)

DEXTER ENDOSCOPE ARM and ARTip solo has the same indications for use as the already cleared SOLOASSIST II.

7. Technological Comparison

21 CFR 807.92(a)(6)

From a technological point of view, the 3 modified robotic arm systems are almost identical to the already cleared SOLOASSIST II (K200473). Also the modified voice control unit “ARTip solo voice” is almost identical to the already cleared VOICE CONTROL (K200473).
All comparable devices have an electromechanical drive and are powered by electricity. The same POWER SUPPLY with the same input and output voltage is used for all devices. The control unit is located inside the device. The devices have the same number of motorized axes and degrees of freedom. The movement is controlled by software. Dimensions and weight are identical.

The following points force the technological differences between the models.
The modified SOLOASSIST II variant differs from the cleared one by the JOYSTICKs and the software version. Compared to the previous version, some specifications regarding the software have been changed or added, e.g the parameter for the SOLOASSIST IID. Furthermore, bug-fixes are included. The software has been verified. There is no negative influence on the safety and performance of the device. In addition, the USB dongle on the VOICE CONTROL has been covered with a protective cap to increase security against unauthorized access. Also there were two new variants of the joysticks with separate MOUNTs and ADAPTERs (see Submission Q210310).

DEXTER ENDOSCOPE ARM / SOLOASSIST IID is another model variant of the SOLOASSIST II. Instead of the VOICE CONTROL, the device can be controlled with a custom device in addition to operation with the JOYSTICKs.
In addition, other reprocessable components are used to hold the endoscope, but these are comparable.
The design of the CANTILEVER in conjunction with the PROBE PIN corresponds to the function of the UNIVERSAL JOINT. In contrast to the UNIVERSAL JOINT, the CANTILEVER is longer and higher and the PROBE PIN including the tracer pin can be removed and replaced by the JOINT. During use, the CANTILEVER is used in conjunction with the JOINT, the ENDOSCOPE CLAMP and the TENSION SLEEVE D5 or D10.
By removing the PROBE PIN and using the JOINT as a new component, it is ensured that the TENSION SLEEVE is still in the CANTILEVER's axis of rotation and an additional rotatable component is available. The longer and higher design and the additional rotatable component ensure that there is no collision with parts of the device when used with the customized device. This has no influence on the function, safety and performance of the device.
The only difference between the ENDOSCOPE CLAMP for the SOLOASSIST IID and the ENDOSCOPE CLAMP of the predicate device is the diameter of the connecting pin. The reason for this is that the ENDOSCOPE CLAMP for the SOLOASSIST IID is only compatible with the JOINT and not with the CANTILEVER, thus preventing the components from being mixed up during connection.
The principle of the plug connections between the components and the materials of the comparable components are identical.
The TENSION SLEEVE D5 or D10, which is connected to the ENDOSCOPE CLAMP, is identical to that of the predicate device. In comparison with the predicate device you have a reduced set of TENSION SLEEVE version (only 5 / 10 mm), but this only limits the use of various endoscopes, because smaller or larger endoscopes cannot be used. This has no impact on the safety and performance of the device.
Compared to the SOLOASSIST II, the inscription on the cover has also been changed.
The software change is the same as described at SOLOASSIST II.

ARTip solo and ARTip solo voice are model variants of the SOLOASSIST II and the VOICE CONTROL. Technologically, the devices only differ in their compatibility with other devices. The ARTip variants of voice control and joysticks are not applicable with the SOLOASSIST II. Likewise, the JOYSTICK-LH, JOYSTICK-RH and VOICE CONTROL are not applicable with the ARTip solo.

Compared to the SOLOASSIST II, the inscription on the cover, the color of the cover and the visual design of the control panel have also changed. In the ARTip solo voice version, the visual design of the front foil has been changed in comparison with the predicate device.
The software change and design change is the same as described at SOLOASSIST II incl. VOICE CONTROL and JOYSTICK-LH/-RH.
The compatibility between the different devices has been checked within the software verification. There is no negative impact on the safety and performance of the device.

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following non-clinical tests were carried out with the predicate devices: Temperature test, force test, lifetime test, moving after fixation, quick release connector test, headset (functional test), movement voice control (functional test), bluetooth reach test, voice commands (functional test) and usability test. The results can also be applied to the new products, which is why the ARTip solo + ARTip solo voice, SOLOASSIST IID and SOLOASSIST II + VOICE CONTROL can be classified as equally safe and effective as the predicate device.

The Cybersecurity of all devices has been evaluated in accordance with the FDA Guidance of September 2023 “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” demonstrating compliance with section 524B of FD&C Act.

In comparison to the predicate device, the following additional tests were carried out to prove the safety and effectiveness with regard to the differences to the predicate device: Verification of the cantilever and its interfaces (for SOLOASSIST IID), packaging validation and software verification (for all new devices).

The non-clinical tests have shown that the SOLOASSIST IID, ARTip solo + ARTip solo voice and SOLOASSIST II + VOICE CONTROL are as safe and effective as the predicate device.