July 20, 2026

Aktormed GmbH
Hanna Kafurke
QM/ Regulatory Affairs Manager
Neugablonzer Strasse 13
Neutraubling, BY 93073
Germany

Re: K261573
Trade/Device Name: Endoscope Holder (182214)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QZB
Dated: May 12, 2026
Received: May 12, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.07.20 09:49:33 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

ENDOSCOPE HOLDER (182214)

Please provide your Indications for Use below.

For the ENDOSCOPE HOLDER as a component of the SOLOASSIST IIS the indications for use of the SOLOASSIST IIS applies.

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

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-05-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	AKTORmed GmbH
Applicant Address	Neugablonzer Strasse 13 Neutraubling BY 93073 Germany
Applicant Contact Telephone	+4994019320150
Applicant Contact	Mrs. Hanna Kafurke
Applicant Contact Email	regulatory@aktormed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ENDOSCOPE HOLDER (182214)
Common Name	Endoscope and accessories
Classification Name	Software Controlled Endoscope And Instrument Holder
Regulation Number	876.1500
Product Code(s)	QZB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233312	UNIVERSAL JOINT, ENDOSCOPE CLAMP, TENSION SLEEVE D5, TENSION SLEEVE D10	QZB

Device Description Summary

21 CFR 807.92(a)(4)

The ENDOSCOPE HOLDER is a sterile disposable product that will be attached to the SOLOASSIST IIS to hold a rigid endoscope/ laparoscope. The SOLOASSIST IIS is technically identical to SOLOASSIST II from K233312 (see Letter to file - SOLOASSIST IIS) The ENDOSCOPE HOLDER consists of 3 main parts (UNIVERSAL JOINT, CLAMP D5 and CLAMP D10). A KNURLED NUT with a screw is used together with the parts to tighten the CLAMPs and therefore fix the laparoscope / endoscope. The main parts are made of MABS, the KNURLED NUT of PA66. All parts are packed together and are sterilized with EO. The product is a sterile device for single use. Functionally, it has the same task as the components of the SOLOASSIST II from K233312 named UNIVERSAL JOINT (REF: 141362), ENDOSCOPE CLAMP (REF: 141363), and TENSION SLEEVEs (REF: 141339 and 141365). The main difference is the reusability as the SOLOASSIST II components are reprocessable while the ENDOSCOPE HOLDER is single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

For the ENDOSCOPE HOLDER as a component of the SOLOASSIST IIS the indications for use of the SOLOASSIST IIS applies.

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

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the ENDOSCOPE HOLDER are the same as for the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

From a functional point of view, the endoscope holding components (ENDOSCOPE HOLDER with UNIVERSAL JOINT and CLAMPs) for SOLOASSIST IIS are almost identical to the already approved components (UNIVERSAL JOINT, ENDOSCOPE CLAMP, TENSION SLEEVEs) for SOLOASSIST II (K233312).
The functionality of the UNIVERSAL JOINT component of the ENDOSCOPE HOLDER is comparable to that of the UNIVERSAL JOINT of the SOLOASSIST II. Both UNIVERSAL JOINTs are attached to the arm system through the STERILE COVER. The attachment and release mechanisms are identical. In addition, both have a plug connection to the endoscope-holding components. Touching the trocar point with the tips is also done in the same way.
The CLAMPs are comparable to the ENDOSCOPE CLAMP in combination with the TENSION SLEEVEs. In both variants, the endoscope is threaded on and secured using a screw and clamp mechanism.
The minor differences in the connections between the components due to design differences were thoroughly tested in a usability study and found to be at least as safe.
Both endoscope-holding connections can bear the same working load. The different mechanical load capacities resulting from the different components and materials used were classified as at least equally safe in corresponding bench tests, meaning that the same working load can be achieved.
In terms of dimensions, both connections are similar and differ only slightly due to design.

The following points force the technological differences between the models. The main difference is the reusability of the components. While the ENDOSCOPE HOLDER is supplied sterile and is for single use only, the components for SOLOASSIST II are reprocessible and therefore reusable. Due to the different manufacturing process and desired reusability, different materials were used. The materials of the ENDOSCOPE HOLDER were sufficiently tested for their suitability in terms of EO sterilization, packaging and shelf life and were found to be at least as safe. Proof of sufficient safety with regard to biocompatibility is available. The choice of other materials therefore also leads to differences in weight.
Differences in the clamping range are due to the different components. Suitable endoscope diameters were verified in corresponding bench tests.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following non-clinical tests were carried out to demonstrate that the new device is as equally safe and effective as the predicate devices. The test results from K233312 cannot be applied to the new products because the products differ in terms of materials, manufacturing and also a bit about how to use it. So new tests were conducted: Human factor testing according to IEC 62366-1/60601-1-6, functional tests, load tests based on IEC 60601-1, compatibility tests, clamping range tests, reuseability tests and packaging tests based on ISTA 1A.

Not Applicable

The non-clinical tests have shown that the ENDOSCOPE HOLDER is as safe and effective as the predicate devices.