April 25, 2024

AKTORmed GmbH
Hanna Kafurke
Regulatory Affairs/Quality Management
Neugablonzer Strasse 13
Neutraubling, BY 93073
Germany

Re: K232405
Trade/Device Name: Endofix Exo
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCV
Dated: August 1, 2023
Received: August 10, 2023

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: 2024.04.25 16:18:53 -04'00'

Mark Trumbore
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)*

K232405

Device Name

ENDOFIX EXO (171943)

Indications for Use *(Describe)*

The ENDOFIX EXO is indicated for use in interventions where a rigid endoscope / exoscope is indicated for use. The device is intended to hold and position a rigid endoscope / exoscope during general and neurological diagnostic and therapeutic procedures.

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)

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Dokumentennummer / *Document Number*	Q002-244988
Version / *Version*	00
Ersteller / *Created by*	Hanna Kafurke
Erstellt Datum / *Created Date*	22.04.2024
Dokumentenname / *Document name*	510(k) Summary
Ablageort / *File*	1DA9486B9E2CC68

freigegeben / released 22.04.2024

Funktion	Name	Datum	Signatur	Vermerk
QM / Regulatory Affairs	Hanna Kafurke	22.04.2024	Hanna Kafurke Q002-244988-00 22.04.2024 15:20:27	erstellt/created
Geschäftsführer Managing Director	Robert Geiger	22.04.2024	Robert Geiger Q002-244988-00 22.04.2024 15:20:36	freigegeben/released

Version / *version*	Änderung / *Changes*	Name / *name*	Datum / *Date*
00	Erstellung / *created*	HK	22.04.2024

510(k) Summary

Inhaltsverzeichnis / contents

1. 510(k) Summary

510(k) Number: K232405

2. 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

3. Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ENDOFIX EXO (171943)
Common Name	Endoscope and accessories
Classification Name	Endoscope Holder
Regulation Number	876.1500
Product Code	OCV

4. Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	K190576
Predicate Trade Name (Primary Predicate is listed first)	WalterLorenz Surgical Assist Arm Scope Holder
Product Code	OCV

5. Device Description Summary

21 CFR 807.92(a)(4)

The ENDOFIX EXO is a manually operated surgical device intended to hold endoscopes during general and neurological diagnostic and therapeutic procedures. It emulates an arm which is capable of guiding and positioning an endoscopic camera with several degrees of movement.
It ensures stable and sensitive positioning of the endoscope and allows the surgeon to work one-handed and/or two-handed. The system provides surgeons with a stable and rocksteady field of vision, even in extreme endoscopic positions. The wide scope of movement provides surgeons with full visibility of the situs. The ENDOFIX exo can be used with both, an endoscope and exoscope.
An integrated DEACTIVATION PUSHBUTTON permits manual movement of the ENDOFIX EXO at the push of a button. In order to reposition a guided endoscopic camera, the ENDOFIX EXO is unlocked by a sterilizable CONTROL at the push of a button. The ENDOFIX EXO is operated by unlocking all 6 axes and subsequent manual positioning using the CONTROL. As soon as the button on the CONTROL is released, all 6 axes are locked again.
Despite its large scope of movement, the ENDOFIX EXO is light-weight and compact and is fastened directly to the OR table by means of a quick-acting clamp. Thus, repositioning with reference to the patient is not necessary even if the OR table is moved in the meantime.
On the rigid endoscope, 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 ENDOFIX EXO.
To allow the surgeon to convert to an open surgery in case of an emergency, the ENDOFIX EXO can be completely mounted or removed by a quick fastener.

During use, the ENDOFIX EXO is covered with a STERILE COVER.
The ENDOFIX EXO can be removed from the OR table and stored on the TROLLEY.

6. Intended use/Indications for Use

21 CFR 807.92(a)(5)

The ENDOFIX EXO is indicated for use in interventions where a rigid endoscope / exoscope is indicated for use. The device is intended to hold and position a rigid endoscope / exoscope during general and neurological diagnostic and therapeutic procedures.

7. Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are very similar for both devices. Both devices have the same intended use, which is the fixation of an endoscope in a position. The ENDOFIX EXO is for use during general and neurological diagnostic and therapeutic procedures. The WalterLorenz Surgical Assist Arm can be used in general and neurological, diagnostic and therapeutic procedures. However, this does not create a new intended use, since the type of use is identical for both devices. For WalterLorenz Surgical Assist Arm Scope Holder the user is a trained medical professional, for ENDOFIX EXO the user is defined as a trained surgeon performing the operation. Both statements mean the same thing, they are just worded differently. The Patient group for the ENDOFIX EXO is all patients, who are suitable within the scope of indications for use. There are no known patient limitations for the WalterLorenz Surgical Assist Arm Scope Holder. Both devices should only be used in professional healthcare environment.

8. Technological Comparison

21 CFR 807.92(a)(6)

Both products have for the most part the same technological characteristics:
Both devices have a permanently installed unlock button, which releases all locks so that the arm can move freely. The unlock button of the ENDOFIX exo is called DEACTIVATION PUSHBUTTON and is located at the distal end of the arm. In contrast, the button of the WalterLorenz Surgical Assist arm is located on the Control Box with User Interface Keypad. However, both devices have a second control panel with an unlock button that is connected to the base unit of the arm via a cable. The control unit of the WalterLorenz Surgical Assist Arm is a sterile, disposable accessory that is supplied separately and can be attached to the distal end of the arm as a release button. The CONTROL of the ENDOFIX EXO is slid over the magnetic bracket of the endoscope clamp and secured from slipping off by a magnetic attraction. When the status LED next to the DEACTIVATION PUSHBUTTON indicates, the CONTROL is ready to operate. This does not happen until the CONTROL is on the magnetic bracket of the endoscope clamp, because there is a sensor in the CONTROL that detects the magnet and only then activates the CONTROL. This increases safety for the patient, as the locks cannot be released if the CONTROL is not on the endoscope clamp. For both devices the Energy Source is Electricity and both do not emit energy. The Locations of the control units are in the devices.
The ENDOFIX exo as well as the WalterLorenz Surgical Assist Arm can be fixed on U.S. table rails.
They have no software and do not include biologics, drugs, coatings and additives. For both devices, the sterilizable accessories can be sterilized by steam sterilization and cleaned by wiping disinfection.
Regarding the power supply, both devices have the identical input voltage of 100-240 VAC; 50-60Hz and the operating mode is continuous.

Nevertheless, there are few differences of technological characteristics:

The first difference is the mechanism of action of the two devices. While the WalterLorenz Surgical Assist Arm uses electromechanical brakes in the axes, the ENDOFIX EXO uses electromagnetic brakes to lock movement in all axes. However, there are no safety or effectiveness implications or other safety issues arising from this difference, as the electromagnetic locks have been mechanically tested according to IEC 60601-1:2005 + A1:2012. In addition, the displacement after fixation of the arm has also been tested. From both tests, there are no risks regarding the safety of the arm.

The ENDOFIX EXO is compatible with endoscopes and exoscopes. For the WalterLorenz Surgical Assist Arm Scope Holder, no exact specification of which scopes are compatible could be found. By specifying exactly which scopes are compatible, the ENDOFIX EXO has at least an equivalent level of safety in terms of compatibility with devices as the WalterLorenz Surgical Assist Arm Scope Holder.
The ENDOFIX EXO's safe working load is specified as 1kg, it was even tested with 5kg and no problems occurred. No defined safe working load was found for the WalterLorenz Surgical Assist Arm.
The WalterLorenz Surgical Assist Arm is battery powered. The ENDOFIX EXO, on the other hand, does not have a battery, which means that there is no risk of the battery failing during an operation and the safety of continuous power operation is ensured. However, this means that the ENDOFIX EXO can no longer be moved in the event of a power failure, but it has been assured that the arm will continue to hold the endoscope in a fixed position. In the event that power cannot be restored by reconnection, both the endoscope itself and the device can be safely and quickly removed from the patient using quick-release fasteners as described in the instructions for use.
The weights of the two devices differ significantly. The ENDOFIX EXO weighs 26.5lbs, the WalterLorenz Surgical Assist Arm without the Scope Holder 8lbs. However, the higher weight does not lead to an increased safety risk, as the ENDOFIX EXO is equipped with a counterbalance to compensate for the weight of the endoscope and the camera head. In addition, the ENDOFIX EXO is mounted to the operating table so that no weight has to be carried by one person. If the ENDOFIX EXO has to be transported over a long distance, it can be mounted on the trolley provided for this purpose and then only needs to be pushed. A usability test was also conducted with 15 American physicians, where weight was not mentioned negatively.
The output voltage of the two devices varies slightly. The ENDOFIX EXO has an output voltage of 24V DC and the WalterLorenz Surgical Assist Arm has an output voltage of 18V DC. However, the ENDOFIX EXO has been sufficiently tested according to IEC 60601-1 for electrical safety to state that it poses no danger to the user.
The last difference is that the distal unlock button of the WalterLorenz Surgical Assist Arm is a single-use product and comes sterile packed. The control unit of the ENDOFIX EXO, on the other hand, can be used more often, but must be cleaned and sterilized before the first use. The complete validation of the reprocessing and sterilization process confirms that there is no increased risk.

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

21 CFR 807.92(b)

The following tests were performed:
1. Lifetime test
2. Lifetime test CONTROL
3. Moving after fixation test
4. Usability test
5. Package drop test

Nonclinical performance tests of the substantial device are unknown. Therefore own nonclinical performance tests were successfully performed to demonstrate the safety and efficiency of the ENDOFIX EXO.

The non-clinical tests have shown that the ENDOFIX EXO device is as safe and effective as the predicate device. For the WalterLorenz Surgical Assist Arm there are unfortunately no informations on which non-clinical performance tests have been performed. However, since the WalterLorenz Surgical Assist Arm is only a Class 1 device, it can be assumed that all non-clinical performance tests for the ENDOFIX EXO are sufficient to ensure at least equivalent safety.