June 5, 2019

Biomet Microfixation
Lauren Jasper
Regulatory Affairs Project Manager
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K190576
Trade/Device Name: WalterLorenz Surgical Assist Arm Scope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 4, 2019
Received: March 6, 2019

Dear Lauren Jasper:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer R. Stevenson
Acting Division 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)*
K190576

Device Name
WalterLorenz Sugical Assist Arm Scope Holder

Indications for Use *(Describe)*
The WalterLorenz Surgical Assist Arm Scope Holder is a manually operated surgical device intended to hold scopes (such as endoscopes, arthroscopes, etc) and accessories during general diagnostic and therapeutic procedures. The device is also intended to hold endoscopes during diagnostic and therapeutic neurologic 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K190576

Prepared June 3, 2019

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Regulatory Affairs Project Manager
lauren.jasper@zimmerbiomet.com
Telephone: (904) 741-9259
Fax: (904) 741-9425

Device Name: WalterLorenz Surgical Assist Arm Scope Holder

Common or Usual Name: Scope Holder

Classification Name: Endoscope and Accessories

Primary Device Classification:

Product Code	Classification Name	Device Classification	Regulation Number	Regulation Description
OCV	Endoscope Holder	2	876.1500	Endoscope and Accessories

Secondary Device Classification:

Product Code	Classification Name	Device Classification	Regulation Number	Regulation Description
GCJ	Laparoscope, General & Plastic Surgery	2	876.1500	Endoscope and Accessories

Indications for Use: The WalterLorenz Surgical Assist Arm Scope Holder is a manually operated surgical device intended to hold scopes (such as endoscopes, arthroscopes, etc) and accessories during general diagnostic and therapeutic procedures. The device is also intended to hold endoscopes during diagnostic and therapeutic neurologic procedures.

Device Description: The WalterLorenz Surgical Assist Arm Scope Holder is a manually operated surgical instrument intended to hold scopes (such as endoscopes, arthroscopes, etc) in a desired position during diagnostic, therapeutic, and surgical procedures (including neurologic procedures). The holder is manufactured from Stainless Steel and functions by the user manually tightening or

loosening a knob, which opens and closes around a surgical scope. The device is intended to attach to the WalterLorenz Surgical Assist Arm, which is a Class 1, table-mounted, electromechanical holding arm that has many general surgical functions in addition to scope holding; it can also be used for instrument holding, retraction, and positioning.

Predicate Devices:
Primary Predicate: K990334, KSEA (Karl Storz) Endoscope Holder
Secondary Predicate: K070509, Fisso Holding Arm

The similarities of the subject device to the predicate devices are as follows:

- The indications for use are similar to that of the predicate devices.
- The range of scope diameters accepted by the scope holder is similar to that of the predicate devices.
- The sterility of the subject device is identical to that of the predicate devices.
- The material of the subject device is similar to that of the predicate devices.

Non-Clinical Performance Data: Non-clinical testing met all established acceptance criteria.

Clinical Performance Data: Clinical testing was not necessary for the determination of substantial equivalence.

Sterilization Information: The reusable scope holder is provided non-sterile to be sterilized by the end user using steam sterilization.

Substantial Equivalence: The proposed device has similar indications for use as the predicate devices. The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed device is at least as safe and effective as the predicates. It is concluded that the information included in this summary supports substantial equivalence.