September 2, 2020

Aesculap Inc.
Sierra Mertz
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K202124
Trade/Device Name: Aesculap PAS-Port Proximal Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: July 30, 2020
Received: July 31, 2020

Dear Sierra Mertz:

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 and Part 809); 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,

For Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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.

510(k) Number *(if known)*
K202124

Device Name
Aesculap PAS-Port Proximal Anastomosis System

Indications for Use *(Describe)*
The PAS-Port Proximal Anastomosis System is intended to create the aortic anastomosis of aortic autologous vein grafts.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (K202124)

PAS-Port Proximal Anastomosis System

August 20, 2020

COMPANY: Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Sierra M. Mertz
484-635-8513 (phone)
sierra.mertz@aesculapimplants.com
610-791-6882 (fax)

TRADE NAME: Aesculap® PAS-Port Proximal Anastomosis System

COMMON NAME: Implantable clip and delivery system

CLASSIFICATION NAME: Clip, Implantable

REGULATION NUMBER: 878.4300

PRODUCT CODE: FZP

DEVICE CLASS: Class II per 21 CFR 878.4300

PREDICATE DEVICE

PAS-Port Proximal Anastomosis System (K091017)

DEVICE DESCRIPTION

The Aesculap® PAS-Port Proximal Anastomosis System is a mechanical device used to facilitate an aortic vein graft anastomosis. The connector replaces sutures to create a secure, patent, and reproducible anastomosis. The PAS-Port system consists of a connector and a delivery system and is contained in a package that is designed to facilitate attachment of the conduit to the implant, as well as to ensure that the venous conduit (after attachment to the system and before deployment) is kept moist and vital.

INDICATIONS FOR USE

The PAS-Port Proximal Anastomosis System is intended to create the aortic anastomosis of aortic autologous vein grafts.

TECHNOLIGICAL CHARACTERISTICS (compared to predicate devices)

The table below provides a summary of the device technological characteristics comparing the subject device and predicate device. The only change to the device is the change in packaging.

	Subject Device – PAS-Port System **Product Code: FZP** **K202124**	**Predicate Device– PAS-Port System** **Product Code: FZP** **K091017**	
Intended Use	The PAS-Port® System is designed to create an anastomosis between the aorta and a venous conduit.	The PAS-Port® System is designed to create an anastomosis between the aorta and a venous conduit.	Same
Indications for Use	The PAS-Port® System is intended to create the aortic anastomosis of aortic autologous vein grafts.	The PAS-Port® System is intended to create the aortic anastomosis of aortic autologous vein grafts.	Same
Device Deployment	A knob is rotated to deploy the device. The first part of the rotation creates the aortotomy and the second part of the rotation deploys the implant.	A knob is rotated to deploy the device. The first part of the rotation creates the aortotomy and the second part of the rotation deploys the implant.	Same
Introducer Tip	The material for the Introducer Tip is made of SCLAIR 2714 HDPE (High Density Polyethylene).	The material for the Introducer Tip is made of SCLAIR 2714 HDPE (High Density Polyethylene).	Same
Packaging	The PAS-Port® device is packaged within a tray (PETG). The tray is then placed in a blister with Tyvek lid foil and sealed. The blister is placed in a carton.	The PAS-Port® device is packaged within a tray (PETG). The tray is then packed in Tyvek header pouch and sealed. The pouch is placed in a carton.	Different
Sterilization	Gamma radiation (25 – 40 kGy)	Gamma radiation (25 – 40 kGy)	Same
Shelf Life	21 Months	21 Months	Same

PERFORMANCE TESTING

Non-clinical testing was conducted to meet the requirements outlined in ISO 11607-1, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems. All samples met predefined acceptance criteria and passed the packaging validation test activities. The successful results demonstrate that the subject device meets the established acceptance criteria and performs as well as or better than the legally marketed predicate device.

Non-Clinical Testing

Test	Acceptance Criteria	Results
Microbial Barrier Verification	• The packaging must not be damaged • The complete sterile barrier must be intact • All sealed seams must be intact	Pass
Seal Strength Verification	The seal strength must be within the defined range of 1.2 - 10 N/15 mm	Pass
Transport Simulation (verification via visual inspection, product evaluation, and verification via bubble test)	• There must be no fatal damages of the packaging which could cause product damage • The product must remain in its intended position • The product must function and must not have visible damages • The sterile barrier must be intact	Pass
Labeling Visual Inspection	All labeling contents must be intact and legible	Pass
Scanning Verification	All codes must be read using bar code scanner	Pass

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the Aesculap PAS-Port Proximal Anastomosis System is as safe, as effective, and performs as well as or better than the legally marketed predicate device.