December 13, 2021

Aesculap, Inc.
Paul Amudala
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K211572
Trade/Device Name: Aesculap Slim Clip Applier
Regulation Number: 21 CFR 882.4175
Regulation Name: Aneurysm Clip Applier
Regulatory Class: Class II
Product Code: HCI
Dated: November 9, 2021
Received: November 10, 2021

Dear Paul Amudala:

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/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,

Naira Muradyan, Ph.D.,
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K211572

Device Name
Aesculap Slim Clip Applier

Indications for Use *(Describe)*

The slim clip applier is used to open, close and apply permanent/temporary Aesculap YASARGIL titanium aneurysm clips.

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

[as required by 21 CFR §807.92(c)]

K211572

DATE PREPARED:	13 December 2021
SUBMITTER:	**Aesculap®, Inc.** 3773 Corporate Parkway Center Valley, PA 18034 +1 800-258-1946
CONTACT:	Paul Amudala Sr. Regulatory Affairs Specialist 610-984-9303 (phone) 610-417-0839 (mobile) 610-791-6882 (fax)
TRADE NAME:	Aesculap Slim Clip Applier
COMMON NAME:	Aneurysm Clip Applier
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER:	21 CFR 882.4175
PRODUCT CODE:	HCI
REVIEW PANEL:	Neurology
PRIMARY PREDICATE DEVICE:	Aesculap Slim Clip Applier (K180914; April 17, 2018)
REFERENCE DEVICES:	Aesculap Slim Clip Applier (K173271; November 10, 2017) Yasargil, Caspar, Vario Clip Appliers (K940970; January 24, 1995)

DEVICE DESCRIPTION

The Aesculap Slim Clip Appliers are manufactured from stainless steel and are available in various lengths, jaw angulations, with or without latches. This submission intends to add a coating to the previously cleared clip appliers. Each clip applier is individually laser marked with the type of clip designated for use. In addition, at least one identification plug is located within one of the handles to aid in identifying the aneurysm clip designation.

INDICATIONS FOR USE

The slim clip applier is used to open, close and apply permanent/temporary Aesculap YASARGIL titanium aneurysm clips.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Aesculap Slim Clip Applier forceps are substantially equivalent to the predicate Aesculap Slim Clip Applier forceps. The intended use, fundamental scientific principles, and base materials of the clip appliers remain unchanged since last clearance. This submission intends to add a coating to the previously cleared clip appliers.

	Subject Device Aesculap Slim Clip Applier	**Predicate Aesculap Slim Clip Applier**	**Reference Device Aesculap Slim Clip Applier**	**Reference Device Yasargil, Caspar, Vario Clip Appliers**
	K211572	K180914	K173271	K940970 (Vario functionality reference only)
Indications for Use	The slim clip applier is used to open, close and apply permanent/ temporary Aesculap YASARGIL titanium aneurysm clips.	The Aesculap Slim Clip Applier forceps are used for opening, closing, and applying Aesculap YASARGIL aneurysm clips.	The Aesculap Slim Clip Applier forceps are used for opening, closing, and applying Aesculap YASARGIL aneurysm clips.	The Aesculap Titanium Aneurysm clip appliers are used for holding and applying intracranial titanium aneurysm clips.
Clip Applier:				
Base Material	Stainless Steel	Same	Same	Titanium
Type	Standard & Mini & Vario	Standard & Mini	Standard & Mini	Standard & Mini & Vario
Length	70mm, 90mm, 110mm	50mm to 110mm, 120mm and 130mm	50mm to 110mm	90mm
Jaw Angulation	Vario, straight, up & down, left & right	Straight, up & down, left & right	Straight, up & down, left & right	Vario & various
Optional Latch	Yes	Latch or no-latch	No Latch	Latch or no-latch
Designated clips	YASARGIL Titanium Clips only (Standard/Mini)	YASARGIL Titanium or Phynox clips (Standard/Mini)	YASARGIL Titanium or Phynox clips (Standard/Mini)	YASARGIL Titanium Clips only (Standard/Mini)
Non-Sterile	Yes	Same	Same	Same
Clip Designation Feature	Yes (POM-C or Propylux Plug & Laser marking on spring)	Same	Same	POM-C
Coating	Yes	No coating	No coating	No coating

TESTING

There is no change to the base design, functionality or intended use of the clip appliers with added coating. Bench testing results demonstrate that the Aesculap Slim Clip Applier is substantially equivalent to the Aesculap Slim Clip Appliers currently on the market. The bench testing of clip appliers demonstrates that the Aesculap Slim Clip Applier forceps perform as intended and are as safe, effective, and perform as well as the predicate devices.

Performance Test Completed	Test purpose	Results	Conclusion
Verification test for clip opening	To verify the minimum opening width of aneurysm clips meets the requirement.	Pass	The Aesculap Slim Clip Appliers meet the test acceptance criteria.

STERILIZATION: The Aesculap Slim Clip Applier forceps will continue to be provided non-sterile similar to the predicate devices. They are intended to be sterilized prior to use.

BIOCOMPATIBILITY: Testing confirmed that the Aesculap Slim Clip Appliers with added coating are biocompatible.

Test	Summary	Conclusion
Cytotoxicity	Test articles were extracted for 24 hours per ISO 10993-5. All test articles exhibited a reactivity grade of 0. Positive and negative controls behaved as anticipated.	Non-cytotoxic
Sensitization	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	Non-sensitive
Pyrogenicity	The purpose of this assessment is to determine if a test article extract induces a pyrogenic response following intravenous injection in rabbits (temperature rise below 0.5 °C indicates the absence of pyrogens). Based on the assessment per ISO 10993-11, the materials are non-pyrogenic.	Non-pyrogenic
Irritation	All animals appeared normal throughout the study. The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 for both the SC and SO test article extracts.	Normal
Systemic Toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Non-Toxic
Hemolysis	The test article extract was tested *in vitro*. The hemolytic index for the test article extract was 0.0% and the test article extract was considered non-hemolytic.	Non-Hemolytic

CONCLUSION

Aesculap Slim Clip Applier forceps presented in this submission are substantially equivalent in design, intended use, and performance to the predicate and reference devices. The added coating does not raise new questions of safety and effectiveness.