



April 17, 2018

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

Re: K180914
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: April 6, 2018
Received: April 9, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Carlos L. Peña -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K180914

Device Name

Aesculap Slim Clip Applier

Indications for Use (Describe)

The Aesculap Slip Clip Applier forceps are used for opening, closing, and applying Aesculap YASARGIL 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.

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

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510(K) SUMMARY - K180914**Aesculap Slim Clip Applier**

April 06, 2018

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

CONTACT: Paul Amudala
610-984-9303 (phone)
610-791-6882 (fax)
paul.amudala@aesculapimplants.com

TRADE NAME: Aesculap Slim Clip Applier

COMMON NAME: Aneurysm Clip Applier

REGULATION NUMBER: 21CFR882.4175 – Applier, Aneurysm Clip

PRODUCT CODE: HCI

REVIEW PANEL: Neurology

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Aesculap Slim Clip Applier forceps are substantially equivalent to Clip Appliers cleared in Primary Predicate K173271 and Reference Predicate K131500 (including K043041, K003519, K002871, K984109, K983758, K970050, K940970, K922272, K913765, K833652, K833651, K833650, and K772200).

DEVICE DESCRIPTION

The Aesculap Slim Clip Appliers are manufactured from stainless steel (body & jaw). The previously cleared appliers are available in lengths ranging from 50 mm to 110 mm in 10 mm increments. In addition to the straight jaw configuration (0°), the Clip Appliers are available with jaws angled up & down (5° to 15°), left & right (5° to 15°), in increments of 5° in all lengths. This submission intends to add additional lengths of 120 mm and 130 mm in these configurations. This submission intends to add additional jaw angulations of 20° to 45° up and down and 20° to 30° left and right in 5° increments and lengths ranging from 50-130 mm in 10 mm increments. In addition to these configurations, clip appliers with latches will be available in lengths ranging from 70 mm to 110 mm in 10 mm increments with jaw angulations ranging from straight, 5° to 45° up and down and 5° to 30° left and right in 5° increments.

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 Aesculap Slim Clip Applier forceps are used for opening, closing, and applying Aesculap YASARGIL aneurysm clips.

TECHNOLOGICAL CHARACTERISTICS (Compared to the Primary Predicate)

The Aesculap Slim Clip Applier forceps are substantially equivalent to the predicate Aesculap Slim Clip Applier forceps and YASARGIL Aneurysm Clip Applier forceps. The intended use, fundamental scientific principles, and base materials of the Clip Appliers (body and jaw) remain unchanged since last clearance. The additional Aesculap Slim Clip Applier forceps are offered with optional latches and additional sizes and angulations but function the same as the Primary and Reference predicates.

	Principle Device	Primary Predicate K173271	Reference Predicate K131500 (including K043041, K003519, K002871, K984109, K983758, K970050, K940970, K922272, K913765, K833652, K833651, K833650 and K772200) YASARGIL Aneurysm Clips and Clip Appliers (Clip Appliers only)
Indications	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 YASARGIL Aneurysm Clips are intended for occlusion of cerebral aneurysms in either a temporary or permanent manner. They are applied with Aesculap Clip Appliers, which contain titanium alloy or phynox jaws-
Clip Applier:			
Body Material (Jaw & Body)	Stainless Steel	Stainless Steel	Titanium Alloy (Ti6Al6V) or Stainless Steel
Length	50mm to 110mm, 120mm and 130mm	50mm to 110mm	50mm, 90mm, 70mm, and 110mm
Jaw Angulation	Straight, up & down, left & right	Straight, up & down, left & right	Straight, angled, bayonet
Optional Latch	Yes	No	Yes
Non-Sterile	Yes	Same	Same
Clip Designation Feature	Yes	Same	Same

TESTING

All required testing was completed for the Aesculap Slim Clip Applier forceps. Bench testing results demonstrate that the Aesculap Slim Clip Applier forceps are substantially equivalent when compared to the Aesculap Clip Appliers currently on the market. Bench testing was performed to demonstrate that the Aesculap Slim Clip Applier forceps perform as intended and are safe, as effective, and perform as well as the predicate devices.

Performance Test completed	Methodology	Results	Conclusions
Benchmark Functional Test	(1) Meet required interface and opening width of the aneurysm clip. (2) Successful release of designated aneurysm clip in the craniotomy. (3) Latch functionality	Pass	The devices interfaced successfully with the aneurysm clips while providing the correct opening width. In addition the devices successfully released the aneurysm clips within the craniotomy.
Predicate/Subject Device Comparison Test	Comparison between predicate and subject device ensuring: (1) Required interface and opening width of designated aneurysm clip. (2) Successful performance of the clip applier with the aneurysm clip. (3) Latch functionality	Pass	The performance testing demonstrated that the subject devices are substantially equivalent to the predicate devices.
Usability Test	(1) Ensuring identification of designated clip type for the specific clip applier. (2) Legibility of additional Clip Applier identification features, i.e. company name, article number, and UDI information. (3) Ensuring visualization of surgical site. (4) Ability to grasp, hold, and apply YASARGIL Aneurysm Clip. (5) Latch usability test	Pass	The usability test demonstrated that the subject devices were properly identified and met the usability requirements.

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: There is no change to the patient contacting material of the Aesculap Slim Clip Applier forceps since they are manufactured from the same Stainless Steel as the predicate devices.

CONCLUSION

Aesculap believes that the Aesculap Slim Clip Applier forceps presented in this submission are substantially equivalent in design, materials, intended use, and perform as safe and effective as Aesculap’s currently marketed devices.