510(k) SUMMARY (as required by 21 CFR 807.92)
Yasargil Aneruysm Clips and Clip Appliers

K131500

JAN 2 4 2014

COMPANY:

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

CONTACT:	Kathy A. Racosky 610-984-9291 (phone) 610-791-6882 (fax) kathy.racosky@aesculap.com
TRADE NAME:	Aesculap Yasargil Aneurysm Clips and Clip Appliers
COMMON NAME:	Aneurysm Clip and Clip Applier
REGULATION NUMBER:	882.5200- Clip, Aneurysm 882.4175- Applier, Aneurysm Clip
PRODUCT CODE:	HCH, HCI
REVIEW PANEL:	Neurology

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Aesculap Yasargil Aneurysm Clips and Clip Appliers are substantially to Aesculap's current Yasargil Aneurysm Clips and Clip Appliers (K043041, K003519, K002871, K984109, K983758, K970050, K940970, K922272, K913765, K833652, K833651 and K833650).

DEVICE DESCRIPTION

The Yasargil Aneurysm Clips are designed for temporary or permanent occlusion of vessels during neurosurgical procedures. They are manufactured from either titanium alloy according to ISO 5832/3 or phynox (cobalt alloy) per ISO 5832/7. The clips range in size from 3 mm to 40 mm and are available in straight, curved, angled, bayonet, T-bar, offset T-bar, convex T-bar, concave T-bar, fenestrated, and non-fenestrated styles.

The Yasargil Clip Appliers are manufactured from stainless steel (body) with either a titanium alloy or phynox jaw. The appliers are available in short (50mm), standard (90 mm) and long (110 mm) lengths, as well as straight, angled and bayonet shapes.

INDICATIONS FOR USE

TheYasargil 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.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Yasargil Aneruysm Clips and Clip Appliers are substantially equivalent to the predicate Aesculap Yasargil Aneruysm Clips and Clip Appliers. The subject device is shown to be substantially equivalent and has the same performance characteristic to its predicate devices through comparison in design, principles of operation, intended use, and materials. The Yasargil Aneruysm Clips and Clip Appliers device characteristics are summarized below.

	New device Yasargil Aneruysm Clips and Clip Appliers	Predicate device Yasargil Aneruysm Clips and Clip Appliers K043041nc003519/K002871 K984109/K983758nc970050 K940970/K922272nc913765 K833652/K833651nc833650
Indications	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.	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.
Aneurysm Clip:		
Material	Titanium Alloy (Ti6Al6V) or Phynox (CoCr)	Titanium Alloy (Ti6Al6V) or Phynox (CoCr)
Sizes	3-40 mm (blade length)	2.8-40 mm (blade length)
Design	Fenestrated and non-fenestrated	Fenestrated and non-fenestrated
Blade Style	Straight, curved, offset T-bar, convex T-bar, concave T-bar, or angled	Straight, curved, bayonet, T-bar or angled
Clip Applier:		
Jaw Material	Titanium Alloy (Ti6Al6V) or Phynox (CoCr)	Titanium Alloy (Ti6Al6V) or Phynox (CoCr)
Body Material	Stainless Steel	Stainless Steel
Style	Straight, angled, bayonet	Straight, angled
Length	50 mm, 90mm, and 110 mm	50 mm, 90mm, and 110 mm

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation ofPremarket Notifications (510(k)s)" was completed for Aesculap Yasargil Aneruysm Clips and Clip Appliers. Biomechanical testing results demonstrate the Aesculap Aneruysm Clips and Clip Appliers are substantially equivalent when compared to our aneurysm clips and clip appliers currently on the market. Preclinical testing was performed to demonstrate that the Yasargil Aneruysm Clips and Clip Appliers performs as intended and is safe, as effective, and performs as well as the predicate devices. Testing was conducted in accordance with ISO 9713. The titanium clip closing force tolerance was within 7.5% of the nominal closing force. The Phynox clip closing force tolerance deviated from the standard, as a result, the Phynox clip closing force tolerance was outside the 7.5% nominal closing force. Tensile testing was conducted to validate the T-bar clip strength of the bond between the blade and the spring wire. The Phynox clips withstand 400N and the titanium clips withstand 210N. The tensile test failure is at the closing loop which is the thinnest point ofthe clip. Tensile testing was performed to simulate the applied force to the weld. The weld withstands 30N of force. In addition testing was performed according to the following MRI standards:

- ASTM F2119 Evaluation ofM R Image Artifacts
- ASTM F2182 Measurement of Radio Frequency Induced Heating During Magnetic Resonance Imaging
- ASTM F2213 Qualitative Measurement ofMagnetically Induced Torque in the Magnetic Resonance Environment
- ASTM F2052 Measurement of Magnetically Induced Displacement Force on the in the Magnetic Resonance Environment

The results and evaluation conclude that the device is MR Conditional in 3-Tesla Magnetic Resonance Imaging (MRI) systems according to ASTM F 2503 and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 24, 2014

Aesculap®, Inc.
c/o Ms. Kathy A. Racosky
3773 Corporate Parkway
Center Valley, PA 18034

Re: K131500
Aesculap Yasargil Aneurysm Clips and Clip Appliers
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: II
Product Code: HCH, HCI
Dated: December 12, 2013
Received: December 13, 2013

Dear Ms. Racosky:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131500

Device Name
Yasargil Aneurysm Clips and Clip Appliers

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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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