



Food and Drug Administration
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August 18, 2016

AROS Surgical Instruments Corporation
% Mr. Greg Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K161315
Trade/Device Name: Vein Clamp and Artery Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: July 18, 2016
Received: July 19, 2016

Dear Mr. Greg Holland:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K161315

Device Name
Vein Clamp and Artery Clamp

Indications for Use (Describe)
A surgical instrument used to occlude a blood vessel temporarily.

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."

K161315

5. 510(k) Summary



Submission Date	May 9, 2016
Submitter	AROS Surgical Instruments Corporation 2111 Descanso Newport Beach, CA 92660 TEL: 949-640-9932 FAX: 949-640-9934
Contact Person	Greg Holland Regulatory Consultant to AROS Surgical Instruments Corporation Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.422.3853 FAX: 949.552.2821 EMAIL: greg@regulatoryspecialists.com
Establishment Registration	2085887
Common Name	Vascular Clamp
Trade Name	Vein Clamp and Artery Clamp
Classification Name	Clamp, Vascular
Regulation	870.4450
Class	II
Panel	Cardiovascular
Product Code	DXC
Associated FDA Numbers	K961100
Reason for Submission	Device Modification
Predicate	K961100, Micro Anastomosis Clamps
Manufacturing Site	Bear Medic Corporation 1361 Chika-Machi, Daigomachi Kuju Gun Ibaraki

319-35
Japan
TEL: 81-295 72 1811
FAX: 81-295 72 4157

Special Controls No applicable mandatory performance standards or special controls exist for this device

Description - The Vein Clamps and Artery Clamps are small clamps used in surgery on small blood vessels. This Special 510(k) is being done to expand on the pressures, add a curved design, and change the sterilization process. There are no other changes and the original products cleared under K961100 remain unchanged and are still being sold.

Intended Use - A surgical instrument used to occlude a blood vessel temporarily.

Indications for Use - A surgical instrument used to occlude a blood vessel temporarily

Technological Characteristics - This Special 510(k) is being done to expand on the pressures, add a curved design, and change the sterilization process.

Changes from the original 510(k), K961100

	K961100	Changes
Closing Pressures	19.8 to 60.1 gms	15 to 120 gms
Design	All clamps were straight	Adds curved design
Sterilization	Ethylene Oxide	Radiation

Testing - Biocompatibility using ISO 10993 and FDA guidance document were successfully completed. Closing pressures were measured. Sterilization validation was done to ISO 11137.

Conclusions from non-clinical performance data

After performing non-clinical performance studies, Biocompatibility to ISO 10993, Sterilization Validations and Compression Studies, the data shows that the Vein Clamps and Artery Clamps are substantially equivalent to the predicate.