

Submitter:
Sibel SA

Vascular Clamp
Premarket Notification: Traditional 510(k)

510(k) Summary

Submitter Name: Surgical Instruments Belgium SA
Submitter Address: Chaussée de Tirlemont, 75
5030 Gembloux
Belgium

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Contact Person: Olivier Rouvez

Date Prepared: 30 September 2007

Device Trade Name: Aortic Clamp

Common Name: Vascular Clamp

Classification Name, Number & Product Code: Clamp, Vascular
870.4450
DXC

Predicate Devices: Surgical Vascular Clamp, Walter Lorenz Surgical, Inc.

Device Description and Statement of Intended Use
Description: SIBEL's vascular clamps are composed different styles and a wide variety of lengths, shapes and sizes. The length and angles are design features that can be important to the surgeon to keep the handles and shanks out of the field of vision of the operative site. The vascular clamps are reusable and have ring handles made of stainless steel or titanium with a ratchet closure to adjust the amount of tension applied to the vessel for occlusion or partial occlusion.
Intended Use: The Vascular Clamp is indicated for use for temporary or partial occlusion of blood vessels during open surgical procedures.

Summary of Technological Characteristics
The Vascular Clamp consists of a variety of jaw styles to allow surgeons to choose from based on the anatomy of the site and type of occlusion. The clamps are either fully or partially occluding. Full occlusion clamps stops blood entirely by covering the full vessel. Partial occlusion clamps are placed on part of the vessel to isolate the area to be worked on while

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allowing blood flow to continue in the rest of the vessel. The lengths and angles are design features that can be important to the surgeon to keep the handles and shanks out of the field of vision of the operative site.

A table comparing the Vascular Clamp to the predicate devices is attached.

Conclusion

The information discussed above demonstrates that the Vascular Clamp is substantially equivalent to the predicate device.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.

This summary does not contain any patient identification information.

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Summary of Technical Characteristics

Feature	Vascular Clamp	Surgical Vascular Clamp
510(k) Number	K072834	K973080
Manufacturer	Surgical Instruments Belgium SA	Walter Lorenz Surgical, Inc.
Classification # & Product Code	870.4450 DXC	870.4450 DXC
Intended Use	Temporary or partial occlusion of blood vessels during open surgical procedures.	Temporary occlusion of blood vessels during vascular surgical procedures.
Mode of Action	Jaws applied around the vessel to isolate the operative area. The lengths and angles are design features to keep the handles and shanks out of the field of vision of the operative site.	Jaws applied around the vessel to isolate the operative area. The lengths and angles are design features to keep the handles and shanks out of the field of vision of the operative site.
Reusable	Yes	Yes
Material of Construction	Stainless Steel or Titanium	Stainless Steel
Method of occlusion	Clamp jaws around vessel	Clamp jaws around vessel
Method of Closure Adjustment	Ratcheting handle for user control	Ratcheting handle for user control



JAN - 9 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Instruments Belgium SA
c/o Mr. William F. Greenrose
Official Correspondent & Regulatory Consultant
220 River Road
Claremont, NH 03743

Re: K072834
Vascular Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: December 24, 2007
Received: January 3, 2008

Dear Mr. Greenrose:

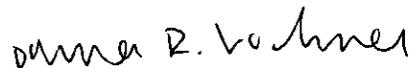
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



 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): K072834

Device Name: Vascular Clamp

Indications For Use:

The Vascular Clamp is indicated for use for temporary or partial occlusion of blood vessels during open surgical procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vechny
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072834