

NY 13020

K973080

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Classification Name:** Vascular Clamp

FEB 23 1998

**Device Classification:** Class II

**Device Product Code:** 74DXC - (CFR 870.4450)

**Intended Use:** These devices are for temporary occlusion of blood vessels during vascular surgical procedures.

**Device Description:** Vascular clamps are made in a wide variety of lengths, shapes, and sizes. 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.

Walter Lorenz Surgical's vascular clamps often have ring handles with a ratchet closure to adjust the amount of tension applied to the vessel for occlusion. Bulldog clamps are another type of vascular cross clamp that use a spring or crossaction mechanism to apply tension to the vessel for occlusion.

The choice of jaw style depends on the surgeon's preference, based on the type and delicacy of the vessel to be occluded. Walter Lorenz vascular clamps employ one of the following jaw styles;

- single row of teeth
- double row of teeth (both jaws) , groove in the center
- single row of teeth on one jaw and double row of teeth on opposite (variation of this style may have additional rows of teeth)
- serrated: horizontal, logitudinal, or crossed
- smooth (variation of this style may have slightly roughed finish)

The surgeon chooses the vascular clamp based on the anatomy of the site and the type of occlusion desired.

Clamps are either fully or partially occluding. Full occlusion clamps stops blood flow entirely by covering the full vessel. Partial occlusional clamps are placed on part of the vessel to isolate the area to be worked on while allowing blood flow to continue in the rest of the vessel.

**Sterility Information:**

The cardiovascular clamps are reusable devices, sterilization of instruments by hospitals is of great concern to Walter Lorenz as a manufacturer and distributor of surgical instrumentation. Since Walter Lorenz is not familiar with individual hospital handling procedures, cleaning methods, or bioburden levels, Walter Lorenz will not assume the responsibility for the sterilization of product by a hospital. General hospital controls for cleaning and sterilization must be up to the user facility. At this time, a package insert has not been drafted for the cardiovascular instrumentation. However, a recommendation on the label for hospitals to use the AAMI Method, SSSA 1988 sterilization guidelines.

**Substantial Equivalence:**

The vascular clamps marketed by competitors displayed in Attachment III, IV, and V are believed to be substantially equivalent to Walter Lorenz vascular clamps for the following reasons:

- The intended uses for devices are equivalent
- The devices have the same technological features
- The safety and effectiveness of the devices are equivalent

**Potential Risks:**

The devices will be sold only to professionals with the knowledge and technical staff trained within vascular surgical disciplines. All devices should be inspected by trained staff prior to sterilization use of reusable surgical vascular clamps. Any risks due to substandard hospital practices will not be listed.

- Trauma to the vessel
- Puncture, tearing of vessel
- Loss of life or limb



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Diana Preston  
Regulatory Specialist  
Walter Lorenz Surgical, Inc.  
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Jacksonville, FL 32229-8009

FEB 23 1998

Re: K973080  
Surgical Vascular Clamp  
Regulatory Class: II (two)  
Product Code: 74 DXC  
Dated: February 3, 1998  
Received: February 4, 1998

Dear Ms. Preston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): unknown

Device Name: Vascular Clamps

Indications For Use: These devices are for temporary occlusion of blood vessels during vascular surgical procedures.



(on Sign-Off)  
Division of Cardiovascular, Res. & Neurological Devices

Number K973080

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)