

JAN 13 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990

AESCULAP VASCULAR INSTRUMENTS

June 17, 1999

Company

Aesculap[®], Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

Contact

Mary Ellen Holden,
Senior Regulatory Associate
Phone: 650-624-5072
FAX: 650-589-3007

Trade Name

Aesculap Vascular Instruments

Common Name

Vascular Clamps, Endoscopic instruments, trocars

Classification Name and Product Code

Vascular Clamps	74DXC
Endoscope and Accessories	78 KOG

Product Classification

Class II

Regulatory Classification

21 CFR Section 876.1500	Endoscope and Accessories
21 CFR Section 870.4450	Vascular Clamp

Intended Use

Aesculap's Vascular Clamps and Instruments are indicated for use in vascular surgery. Alfa and Alfa-mini vascular clamps are designed for temporary occlusion of blood vessels during open surgical procedures. Atraumatic vascular clamps and clamp applicators/removers are designed for temporary occlusion of blood vessels during either an open or endoscopic surgical approach.

Laparoscopic vascular scissors, forceps, clamps, dissecting spatulas and needleholder are use for cutting, dissecting, clamping, fixation and suturing vessels and tubular structures. Flexible trocars provide access to the surgical site for use in laparoscopic vascular surgery.

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Device Description

The Vascular Instruments consist of vascular clamps, flexible trocars, and various endoscopic vascular instruments (scissors, forceps, clamps).

Summary of Technological Characteristics

Aesculap currently markets a complete vascular product line, which includes vascular clamps and instruments. In addition, Aesculap markets a complete endoscopic product line that includes endoscopes, flexible and rigid trocars, endoscopic clip applicators and endoscopic instruments such as forceps and scissors. The expanded line of Vascular Clamps and Endoscopic Vascular Instruments included in this submission do not impart any new technological characteristics. They use the same technology as current vascular and laparoscopic product lines – the only difference is the surgical application.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Substantial Equivalence

Aesculap believes that the Vascular Instruments presented in this submission are substantially equivalent in design, function, and intended use to currently marketed vascular and endoscopic devices from companies such as:

- Aesculap
- Codman
- Heartport
- Mueller
- Walter Lorenz



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ellen Holden
Senior Regulatory Associate
Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

Re: K992053
Trade Name: Aesculap Vascular Instruments
Regulatory Class: II
Product Code: DXC and GCJ
Dated: October 14, 1999
Received: October 15, 1999

Dear Ms. Holden:

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 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). 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

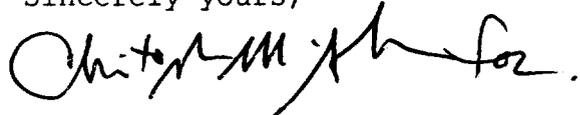
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you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4586. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K992053

Device Name: **Aesculap Vascular Instruments**

Indication for Use:

Aesculap's Vascular Clamps and Instruments are indicated for use in vascular surgery. Alfa and Alfa-mini vascular clamps are designed for temporary occlusion of blood vessels during open surgical procedures. Atraumatic vascular clamps and clamp applicators/removers are designed for temporary occlusion of blood vessels during either an open or endoscopic surgical approach.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christina M. Allen for Witten
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K992053

Prescription Use X
(per 21 CFR 801.109)

or Over-the-Counter Use _____