K981624

AUG 4 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Ave.
St. Paul, MN 55114-1024

Contact: D. E. Gardner, Ph.D.
VP, Regulatory Affairs / Quality Assurance

Date Prepared: May 4, 1998

Common or Usual Name: Intraluminal shunt

Device Classification Name: Clamp, vascular; 870.4450; Class II

Substantial Equivalence:
The device is substantially equivalent to the BVI Flo-Rester vessel occluder, the CTS MIDCAB Coronary Shunt (CTS FloCoil Shunt), the AnastaFLO Intravascular Shunt, DLP Intravascular Arteriotomy Cannula, the Rivetti-Levinson Intraluminal Shunt, and the Chase Blood Vessel Shunt.

Device Description:
The sterile, single-use Flo-Thru Intraluminal Shunt (FTIS) is a one-piece radiopaque silicone tube with atraumatic bulbs shaped at each end. Openings at the ends of the bulbs allow blood to flow through the shunt and distal to the anastomotic site. A radiopaque tab, which identifies the outer diameter of the bulbs, is attached to the shunt by a tether to facilitate positioning and removal of the shunt.

Statement of Intended Use:
The Flo-Thru is indicated for use in coronary artery or peripheral vascular procedures. The device shunts blood at the anastomotic site which provides a temporary blood-free operative field for suturing while allowing blood to flow distal to the anastomosis. The device is removed just prior to the final suturing of the vessel.

Summary/Comparison of Technological Characteristics:
Functional testing conducted on the Flo-Thru intraluminal shunt and predicate samples show the Flo-Thru performs in a manner substantially equivalent with regard to strength, and flow rate. Handling characteristics, flexibility, and radiopacity of the Flo-Thru device meet design requirements. Also, the Flo-Thru has no memory of kinking or manipulation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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D.E. Gardner, Ph.D.
VP, Regulatory Affairs / Quality Assurance
Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024

Re: K981624
Trade Name: Flo-Thru™
Regulatory Class: II
Product Code: DXC
Dated: May 4, 1998
Received: May 7, 1998

Dear Dr. Gardner:

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.

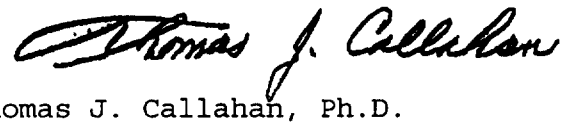
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4586. 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,



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

Enclosure

510(k) Number (if known): K98 1624

Device Name: Flo-Thru™

Indications for Use:

The Flo-Thru is indicated for use in coronary artery or peripheral vascular procedures. The device shunts blood at the anastomotic site which provides a temporary blood-free operative field for suturing while allowing blood to flow distal to the anastomosis. The device is removed just prior to the final suturing of the vessel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K961624

Prescription Use ✓ OR Over-The-Counter Use____
Per 21 CFR 801.109