JUN 1 1999

K991813

Section 2 - Summary & Certification

Date: September 5, 1996

Submitter's Name: Ted Karwoski, VP R&D/Operations
Atrium Medical Corporation

Address: 5 Wentworth Drive
Hudson, NH 03051

Telephone No.: (603)880-1433

Trade Name: Uni-graft® K DV
Vascular Graft 6mm and larger

Safety and Effectiveness Summary

This device is a vascular graft intended for use as a replacement conduit for abdominal, thoracic, and larger peripheral arterial reconstruction. Reconstruction is required because of - 1) aneurysmal disease or potential rupture, and 2) occlusive disease or blockage of the natural vessel.

It is substantially equivalent to the Meadox Hemashield and Vascutek Gelseal and Gelsoft. It is a polyester terephthalate knitted fiber graft coated with modified cross linked gelatin to establish zero porosity or leakage through the wall. Minimizing blood loss is extremely important in large diameter conduits such as the aorta.

Implantation of all vascular grafts have potential adverse patient effects or complications. These involve surgical risk from the operation, graft occlusion (which include thrombosis, technical errors in surgery or anatomic positioning) coagulopathy, infection, thromboembolic episodes (downstream clotting), aneurysm, hyperplasia, leaking or weeping of blood or serous fluid (seroma). In addition, coated grafts can cause immunological (allergic) reactions, delayed healing. Any, and all of these complications can lead to amputation which is the undesirable event the synthetic vascular graft was intended to ameliorate.

Patients undergoing implantation of the Uni-graft® K DV experience no increase in any risk over that of an uncoated polyester prosthesis based upon study results or implantation history of this product in the world marketplace.

The benefits of a gelatin coated product as a vascular replacement are significant in that it does not require preclotting, minimizes blood loss, operative time, substitute blood product exposure, and anesthesia.

All pertinent structural and biological testing such as burst strength, porosity, compliance, etc., parameters detailed in the Vascular graft prostheses guidance and tripartite documents have been completed. The results show equivalent strength and long term structural stability of this product compared to existing devices.

Over 200,000 implants worldwide of the Uni-graft® product have occurred with an exemplary record of success. Various human and animal reports are included in this submission for review. A definitive clinical trial comparing the Uni-graft® to historical coated graft controls was conducted in Japan on 100 patients from 1990 - 1993. This clinical study showed no bleeding, negative collagen antibody testing or complications specifically associated with the Uni-graft® prosthesis at the 6 month study period. The cumulative patency rate was 98.8%. This study as well as the other information provided demonstrates this product to be safe and effective with performance as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

Mr. Joseph P. DePaolo
Director of Regulatory Affairs
Atrium Medical Corporation
5 Wentworth Drive
Hudson, NH 03051

Re: K991813
Uni-Graft® K DV Gelatin Coated Vascular Graft
Regulatory Class: II (Two)
Product Code: DSY
Dated: April 20, 1999
Received: May 18, 1999

Dear Mr. DePaolo,

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) 594-4648. 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" (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

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): K991813

Device Name: Uni-Graft K DV Vascular Graft

Indications For Use:

The Uni-Graft K DV is indicated for use in repair or replacement of damaged and diseased vessels of the abdomen in cases of aneurysmal or occlusive disease.

(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

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)