

KC110851

ATTACHMENT # 1.
510 (k) Summary of Safety and Efficacy -
Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory

NOV - 5 1997

Submitted by: Sherwood - Davis & Geck
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Contact: Vanada Johnson
Date Prepared: 4 March, 1997

The Argyle® Aqua-Seal® All Purpose Autotransfusion Chest Drainage Unit (CDU) and Argyle® Aqua-Seal™ Evacuating Autotransfusion Accessory (Evacuating Accessory) is classified as an "Auto-transfusion Device", Class II (performance standards) under section 868.5830 of the Code of Federal Regulations (CFR).

The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory is a sterile, single-use accessory to the Argyle® Aqua-Seal® All Purpose Autotransfusion CDU and is intended to be used for the purpose of transferring the lost blood recovered by the CDU into a conventional blood bag. The blood can subsequently be re-infused back into the patient using a conventional pressure cuff or by gravity means.

The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory consists of a conventional blood bag contained in an air-tight vessel. The input line from the bag passes through a sealed opening located at the top of the vessel. This line attaches to the spike port "Y" connector of the infusion tube assembly of the CDU. Transfer of blood from the CDU to the bag commences when a vacuum line is removed from the CDU and attached to the suction port of the Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory. The pressure differential across the surface of the bag compels the bag to expand and thereby drawing blood from the CDU into the bag.

The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory is substantially equivalent to the Atrium Self-Sealing ATS bag in that:

1. Each device allows for the batch transfer of a patient's lost post-operative blood from the CDU into an external container bag.
2. Each device operates on the principle that fluid will rush to fill a vacuum. The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory utilizes hospital vacuum while the Atrium Self-Sealing ATS bag creates its own vacuum by means of a spring.
3. Each device is designed for single use only.

The differences between the Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory and the Atrium Self-Sealing ATS bag are:

1. The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory operates on hospital vacuum while the Atrium Self-Sealing ATS bag utilizes the stored potential energy of a fully compressed metal spring.

2. The Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory is a conventional PVC blood bag. The Atrium Self-Sealing ATS bag is thick PVC and inflexible because of the pressure plates and spring built within. As such the Atrium Self-Sealing ATS bag will not fit in a conventional pressure cuff.

In addition, the Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory has undergone testing to ensure that the device meets the applicable blood handling requirements outlined in the American National Standards Institute (ANSI) / Association for the Advancement of Medical Instrumentation (AAMI) Standard for Autologous devices. Biocompatibility testing in accordance with ISO 10993 requirements has been done, as has performance testing under simulated conditions of use. Results of all testing demonstrate the safety and effectiveness of the Argyle® Aqua-Seal® Evacuating Autotransfusion Accessory for its intended use.

The Argyle® Aqua-Seal® All Purpose Autotransfusion Chest Drainage Unit is also substantially equivalent to the Argyle® Aqua-Seal® Continuous Autotransfusion Chest Drainage Unit and to the Atrium Multipurpose Chest Drainage Unit in design, function and appearance. The only differences between the two are:

1. The Argyle® Aqua-Seal® All Purpose Autotransfusion CDU incorporates the automatic negative pressure relief valve with a manual override feature whereas the Argyle® Aqua-Seal® Continuous Autotransfusion CDU and the Atrium Multipurpose CDU utilize a strictly manual negative pressure relief valve.
2. While all three CDU's incorporate shut-off valves to prevent the loss of the water seal, the shut-off valves on the Argyle® Aqua-Seal® All Purpose Autotransfusion CDU and the Atrium Multipurpose CDU are flow sensing. Therefore, at low flow rates associated with the autotransfusion process, the valve "shuttles" and remains open to allow for improved blood collection times.

The Argyle® Aqua-Seal® All Purpose Autotransfusion Chest Drainage Unit with the two new features has undergone testing to ensure that the device meets the applicable blood handling requirements outlined in the American National Standards Institute (ANSI) / Association for the Advancement of Medical Instrumentation (AAMI) Standard for Autologous devices. Biocompatibility testing in accordance with ISO 10993 requirements has been done, as has performance testing under simulated conditions of use. Results of all testing demonstrate the safety and effectiveness of the Argyle® Aqua-Seal® All Purpose Autotransfusion CDU for its intended use.



Food and Drug Administration
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444 McDonnell Boulevard
Hazelwood, Montana 63042-2516

NOV - 5 1997

Re: K970857
Argyle® Aqua-Seal All Purpose Autotransfusion Chest Drainage Unit
Regulatory Class: II (Two)
Product Code: CAC
Dated: August 6, 1997
Received: August 7, 1997

Dear Mr. Johnson:

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 (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.

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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): K970857

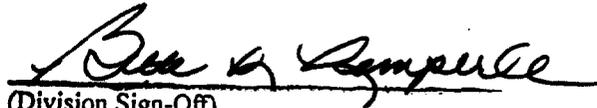
Device Name: S 001

Indications For Use:

1. Evacuation and collection of blood and/or air from the mediastinal and pleural cavity in post-operative and trauma situations.
2. Collection and reinfusion of autologous blood from the mediastinal and pleural cavity in post-operative and trauma situations.
3. Prevention of fluid and/or air re-accumulation in the mediastinal and pleural cavity.
4. Facilitation of complete lung re-expansion and restoration of normal breathing dynamics.

(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 K970857

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____