510k Summary of Safety and Effectiveness

K972139

Argyle® ASPR-Care™ Closed Suction System Accessory Manual Resuscitation Bag Adapter:

Submitted by : Sherwood Davis and Geck
444 McDonnell Blvd.
Hazelwood, MO 63042

SEP - 3 1997

Contact: Stephen J. Tamsett,
Regulatory Affairs Manager

Date of Summary: May 31, 1997

The Argyle ASPR-Care Manual Resuscitation Bag Adapter is an accessory to the Argyle Closed Suction System. The Argyle ASPR-Care Closed Suction System has been determined to be Substantially Equivalent to the Devices marketed in interstate commerce prior to May 28, 1976 under 510k, K955831. The adapter provides the trained clinician with an accessory that facilitates the manual ventilation of the patient, without requiring the opening of the ventilator circuit or removal of the closed suction system from a patient 's artificial airway. The accessory is designed for use strictly with the Argyle ASPR-Care Closed Suction System.

The accessory was tested for the time to alarm with various ventilators. The test was completed after insertion of the Manual Resuscitation Bag Adapter through the Dual Swivel T-Piece accessory port. For all ventilators tested in this manner, the time to alarm was instantaneous upon installing the adapter without a bag. When the adapter was installed with a bag attached the alarm went off at the beginning of the next breathing cycle. This was verification that the accessory worked properly when incorporated into the patient's artificial airway.

Per ISO 10993 and ANSI/AAMI 10993 the component has been tested for Biocompatibility. The materials are the same and were also used and tested in 510k, K955831 for the Argyle ASPR-Care Closed Suction System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP - 3 1997

Mr. Stephen J. Tamsett
Sherwood Davis & Geck Medical Company
444 McDonnell Boulevard
Hazelwood, Missouri 63042-2516

Re: K972139
Argyle™ ASPR-Care™ Closed Suction System
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: May 31, 1997
Received: June 6, 1997

Dear Mr. Tamsett:

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.

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

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) K972139

Device Name: Sherwood-Davis & Geck ASPR-Care™ Manual Resuscitation Adapter; Accessory

Indications for Use: The Device allows for the connection of a manual resuscitation bag without the disconnection of the ventilator circuit/system or the removal of the ASPR-Care™ CSS dual swivel T-piece connector.

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A. Ciarlowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972139

Prescription Use ✓ OR (Per 21 CFR 801.109)

Over-the-Counter Use _____ (optional format 1-2-96)