MAY 1 8 1998

K974015

510k Summary of Safety and Effectiveness

Argyle® Quick PICC Neonatal/Pediatric Peripherally Inserted Central Cathter and Accessories

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

Contact: Stephen J. Tamsett,
Regulatory Affairs Manager

Date of Summary: October 17, 1997

The Argyle Neonatal/Pediatric Peripherally Inserted Central Catheter (PICC) is a sterile, single use indwelling catheter inserted into a venous access site for the infusion of fluids, medications, and/or nutritional products.

The PICC is inserted via an introducer (either a splittable needle or sheath over the needle type). The catheter is composed of polyurethane material and includes a suture or stabilizing wing and an insert-molded luer-lock hub(s). The catheters will have numerical depth markings for insertion depth measurement and assessment. The polyurethane material is completely radiopaque.

Additionally, the product line will include for sale the following: single catheters, single introducers, placement sets (catheter and introducer), and complete insertion trays. Complete insertion trays will contain a PICC, introducer, and common components used for the procedure.

The Argyle Neonatal/Pediatric PICC is substantially equivalent to Bard Access System's Per-Q-Cath PICC. The Argyle PICC differs from the Bard PICC in that Bard's product is manufactured from silicone, while the Argyle PICC is manufactured from polyurethane.

The Argyle Neonatal/Pediatric PICC is substantially equivalent to Luther Medical Company's L-Cath PICC in that both are manufactured from polyurethane.

Required biocompatibility testing has been performed per ISO 10993 and ANSI/AAMI 10993 for components. The materials are the same and were also used and tested in previously submitted and marketed 510k's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Mr. Stephen Tamsett
Manager of Regulatory Affairs, USA
Sherwood Davis & Geck
444 McDonnell Boulevard
Hazelwood, Missouri 63042-2516

Re: K974015
Trade Name: Argyle Quick-Picc Peripherally Inserted Central Catheter and Accessories
Regulatory Class: II
Product Code: FOZ
Dated: February 25, 1998
Received: February 26, 1998

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 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K974015

Device Name: Sherwood-Davis & Geck Argyle® Quick-PICC™ Neonatal/Pediatric Peripherally Inserted Central Catheter and Accessories:

Indications for Use: The Quick-PICC Catheter System is designed for cases in which venous catheterization or long term I.V. administration is necessary. Placement is routinely achieved from a peripheral venous site, but the catheter may be placed via subclavian cut-down as well. The Quick -PICC may be used to administer fluids for hydration and parenteral nutrition, as well as other commonly used intravenous medications such as antibiotics, vasopressors, chemotherapy, and analgesics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109)

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

(Division Sign-off)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K974015

510(k) Number _____