FEB 2 7 1998

510k SUMMARY OF SAFETY AND EFFECTIVENESS

Kangaroo® Enteral Extension Set for Syringe Pumps

Submitted by: Sherwood-Davis & Geck
444 McDonnell Blvd.
Hazelwood, MO 63042-2516

Contact: Vanada Johnson
Regulatory Affairs Specialist

Date of Summary: September 5, 1997

The Kangaroo® Enteral Extension Set for Syringe Pumps is an Enteral Feeding Administration Set composed of a PVC material and is a class II device per 21 CFR Section 876.5980. Procode: 80FRN.

The Kangaroo® Enteral Extension Set for Syringe Pumps has a non-IV compatible distal connector which when connected to a syringe allows enteral formula to be administered through an enteral feeding tube. The Kangaroo® Enteral Extension Set for Syringe Pumps is indicated for single use enteral feedings .

Similarities between the proposed Kangaroo® Enteral Extension Set for Syringe Pumps and the currently marketed Kangaroo® Pump Sets are 1) both extension sets are used for administering enteral feedings, 2) both extension sets are made of PVC material, 3) both extension sets are EtO sterilized and 4) both extension sets have a non-IV compatible connector.

The differences between the proposed vs. the predicate device is 1) the proposed extension set will vary in length from the predicate device and 2) the proposed device will be packaged in a tyvek/polyethlene tray vs. a low density polyethylene bag.

The following battery of tests were performed in accordance to respective guidelines and deemed acceptable - Biological Reactivity, In-Vitro, (USP XXIII <87>), Dermal Sensitization (ISO 10993-10.2 (draft)) and Primary Mucosal Irritation (FDA Good Laboratory Practice guidelines, 19, revision 5; GCPT-19.(5).

Sherwood-Davis & Geck considers the Kangaroo® Enteral Extension Set for Syringe Pumps substantially equivalent to a family of predicate devices, the Kangaroo® Enteral Extension Set for Pumps covered under 510k K914375, Entri-Flex® Feeding Tubes covered under K833621, Dobbhoff ® Feeding Tubes covered under K833188, Entri-Flex® Feeding Tubes w/flexible weight covered under 510k K801558 and Pedi-Tube Pediatric Feeding Tubes covered under 510k K822875.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Ms. Vanada Johnson
Regulatory Affairs Specialist
Sherwood, Davis & Geck
444 McDonnell Blvd.
Hazelwood, MO 63042-2516

Re: K973409
Kangaroo® Enteral Feeding Extension Set
for Syringe Pumps
Dated: January 12, 1998
Received: January 13, 1998
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT

Dear Ms. 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 requirement, 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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name: Sherwood-Davis & Geck
Kangaroo® Enteral Feeding Extension Set for Syringe Pumps

Indications for Use: The Kangaroo® Enteral Feeding Extension Set for Syringe Pumps is intended for enteral feeding, on the order of a physician, to provide a means of delivering feeding formula from a filled syringe through to any feeding tube which will accept its non-I.V. compatible connector.

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

Concurrenc of CDRH, Office of Device Evaluation (ODE)

Robert R Catlin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973409

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-off)

510(k) Number _____