K971230

JUN 13 1997

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SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

Submitter: InnerDyne, Inc.
5060 West Amelia Earhart Drive
Salt Lake City, Utah 84116
Estab. Reg. No: 1721520

Date Prepared: 15 March 1997

Contact: Rick Gaykowski
Vice President, Regulatory Affairs
and Quality Assurance

Sponsor: Sherwood Medical Company
1915 Olive Street
St. Louis, MO 63103
Estab. Reg. No.: 1924954

Classification Name: Gastrointestinal Tube & Accessories
Generic Name: Gastrostomy Tube & Accessories
Trade Name: Sherwood Medical Company, Kangaroo®, EntriStar®, "Percutaneous Gastrostomy Kit"

The Kangaroo®, EntriStar®, "Percutaneous Gastrostomy Kit" is a sterile, single use system containing a gastrostomy tube for enteral feeding and the components required to insert the tube percutaneously, which may include endoscopic and/or laparoscopic methodology. The kit consists of a radially expanding access device, gastrostomy tube, obturator, insertion/removal device, "Y" connector, luer adapter, external retention disk, retention band, #11 scalpel, drape, gauze pads, lubricant, and Instruction for Use (IFU).

The radially expanding access device is an expandable dilator sheath assembly with an access needle mounted within its lumen. The tubular member of the dilator sheath is configured so as to be axially compressed to reduce the outside diameter of the device prior to insertion. Upon use, the expanding dilator sheath/needle assembly is inserted through the abdominal tissue into the gastric cavity.

If endoscopic technique is utilized, an endoscope is advanced into the stomach using standard techniques, followed by stomach insufflation. An abdominal incision is made and the access needle/sheath assembly is inserted directly through the abdominal and stomach walls into the stomach. The access needle is removed and the cannula/dilator is advanced through the radially expanding sleeve. If laparoscopic technique is utilized, under laparoscopic vision the abdominal cavity is entered and the stomach site is selected for insertion of the gastrostomy tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Sherwood Medical Company
% Mr. Rick Gaykowski
Corporate Vice President, Regulatory Affairs
and Quality Assurance
InnerDyne, Inc.
5060 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K971230
Sherwood Medical Company, Kangaroo®, EntriStar®, "Percutaneous Gastrostomy Kit"
Dated: March 31, 1997
Received: April 2, 1997
Regulatory class: II
21 CFR §876.5980/Product code: 78 KNT

Dear Mr. Gaykowski:

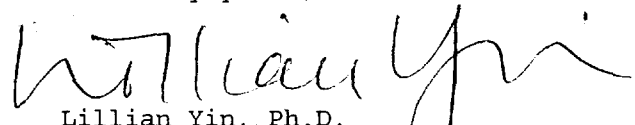
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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): K971230

Device Name: Sherwood Medical Company, Kangaroo®, EntriStar®, "Percutaneous Gastrostomy Kit"

Indications for Use: The Sherwood Medical Company, Kangaroo®, EntriStar®, "Percutaneous Gastrostomy Kit" is a medical device for the percutaneous placement of a long-term enteral feeding tube.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Caroline Y. Neuland for R. Cottling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971230