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510(k) Summary of Safety & Efficacy: Kangaroo® EntriStar™ Skin-Level Gastrostomy Feeding Kit

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The Kangaroo® EntriStar™ Skin-Level Gastrostomy Kit is a sterile, single use device containing a gastrostomy tube and the components needed to insert a low profile gastrostomy tube. The Kangaroo® Skin-Level Gastrostomy Kit is a Class II device, Gastrointestinal Tube and Accessories per 21 CFR 876.5980, Procode: 78KNT.

The Skin-Level Gastrostomy Tube is a replacement gastrostomy tube placed through an existing stoma via the abdomen into the stomach. The tube acts as a conduit to deliver formula to a patient requiring enteral nutrition and as a conduit for insertion of enteral access devices such as gastric decompression catheters or intestinally placed feeding catheters. The stoma tube is designed so that it is a fixed length to correspond to the depth of the stoma. However, a "step-up shim" may be placed between the external retention device and the abdominal wall to customize the fit to the patient.

The Skin-Level Gastrostomy Tube is inserted and removed by inserting the obturator through the inner lumen of the stoma tube. When inserted, the obturator mechanically slenderizes (elongates) the internal retention device, which reduces its diameter to reduce the physical trauma to the stoma inherent in the insertion and removal procedures.

The Skin-Level Gastrostomy Tube is available in various lengths designed to precisely fit the depth of the patient's stoma, which results in a snug fit between the surface of the external retention device and the patient's abdomen. An insertion/removal accessory is included for use when inserting and removing the gastrostomy tube.

The distal tip of the obturator and the internal retention device are covered in lubricious Hydromer coating to reduce the force needed to insert the obturator and gastrostomy tube. Hydromer coating is currently used in several nasogastric feeding tubes marketed by Sherwood and Biosearch Medical Products which were cleared via the 510(k) process.

In accordance with ISO 10993 Part-1 Biocompatibility Guidance, the Kangaroo® EntriStar™ Skin-Level Gastrostomy Kit is categorized as an implantable device, of permanent contact, contacting tissue/bone. Based on this classification, the kit will be required to pass the following battery of tests: Implantation (7 day), Cytotoxicity, Sensitization, Genotoxicity and Chronic Toxicity prior to the release of product for sale. In addition to biocompatibility testing, Sherwood has established functional specifications to ensure the device is safe and effective for its intended use.

Sherwood believes that the Kangaroo® EntriStar™ Skin-Level Gastrostomy Kit is substantially equivalent to the Low-Profile Gastrostomy Device [Biosearch Medical Products, Somerville, NJ] which was cleared as 510K No. K923474. In fact, the device covered by this submission is simply a modified version of the design disclosed in K923474. Both kits utilize the same basic gastrostomy tube design and accessories.