

MAY - 9 1996

510(k) Summary of Safety & Efficacy: Kangaroo® Pedi-Tube Flow Through Stylet & Kangaroo® Flow-Through Stylet

Submitted by: Sherwood Medical Co., 1915 Olive St.,  
St. Louis, MO 63103, (314) 621-7788  
Contact: Dennis Pozzo, Regulatory Affairs Manager  
Date Prepared: January 30, 1996

The Kangaroo® Pedi-Tube Flow Through Stylet & Kangaroo® Flow-Through Stylet are Class II devices per 21 CFR 876.5980.

The Kangaroo® Stylets are comprised of a stainless steel wire that terminates at its distal end welded to an atraumatic stainless steel spring. The proximal end of the stainless stylet wire is mechanically attached to a flow-through male polypropylene luer hub.

The function of the stylet is to provide the necessary stiffness to aid the clinician in the placement of a nasointestinal feeding tube. The stylet is inserted in the feeding tube prior to insertion of the feeding tube in the patient. Once it has been verified that the feeding tube is appropriately placed, the stylet is removed.

The stylets will be sold both sterile & non-sterile and individually & with the following nasointestinal feeding tubes:

- Pedi-Tube Pediatric Feeding Tube - K822875,
- Dobbhoff Feeding Tube w/Hydromer Lubricant- K831868,
- Entriflex Feeding Tube - K833621 &
- Non-Weighted Polyurethane Enteral Feeding Tube - K914375.

The Kangaroo® Stylets are substantially equivalent to Biosearch Medical Products' Feeding Tube Placement Stylet cleared via the 510(k) process, #K831840A in that both share the same design, components and intended use.

The Kangaroo® Stylets are also substantially equivalent to the Pedi-Tube Stylet cleared via the 510(k) process, #K894857 in that both share the same basic design, components and intended use.

The major difference between the stylets is the currently marketed Pedi-Tube Stylet does not contain a flow-through hub or a stainless steel spring tip.

The materials that comprise the Sherwood Stylets will be the same as those that comprise Biosearch's currently marketed Feeding Tube Placement Stylet.