

K970341

510(k) Summary
upon which equivalency is claimed
Medtronic PS Medical Repair Kit
Summary of Safety and Efficacy

APR 23 1997

The determination of safety and efficacy for the Medtronic PS Medical Rivas™ Vascular Catheter Repair Kit is based upon the predicate Bard Davol Repair Kit. The safety and efficacy of design and indications is based upon years of clinical history with vascular access products fabricated from silicone elastomer. The materials utilized in the Medtronic PS Medical Rivas™ Vascular Catheter Repair Kit have demonstrated clinical *in-vivo* safety and efficacy.

The Bard Davol Repair Kit has proven safe and effective for repair of the external segment of a vascular catheter.

Vascular access products are not free from failure. Complications associated with the use of the device may be similar to those experienced in any other similar surgical procedure:

- Reactions to drugs or anesthetic agents;
- Electrolyte imbalance;
- Allergic reaction to materials;

Local and systemic infections are not uncommon with this type of procedure. They are most usually due to organisms that inhabit the skin, particularly *Staphylococcus epidermidis*.

Based upon the summary above, Medtronic PS Medical determines substantial equivalence and safety and efficacy of the Rivas™ Vascular Catheter Repair Kit based upon the predicate and currently marketed devices.