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SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

A. GENERAL INFORMATION

Owner Operator Submitting Boston Scientific Corporation
this Premarket Notification: One Boston Scientific Place
Natick, MA 01757
(508) 650.8174
Contact Person: Wanda M. Carpinella
Regulatory Affairs Department
Device Generic Name: Venous Access Port Kit
Device Classification: 80 LJT, Implanted Subcutaneous Port and Catheter

B. INDICATIONS FOR USE

Implantation of a port and catheter is indicated whenever patient therapy requires repeated intravascular injection or continuous infusion of fluids, medications, antibiotics, nutritionals and the withdrawal of venous blood samples.

C. DESCRIPTIVE CHARACTERISTICS

The device is a vascular access system consisting of an low profile port with an injectable septum and a detached catheter. The low profile port is suitable for arm placement or for implantation in the chest wall. A non-coring, stainless steel needle is supplied with each port.

D. SUBSTANTIAL EQUIVALENCE

The proposed port has been shown to be substantially equivalent to Therex's low profile ports.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

The low profile port is packaged in a PETG blister tray covered with a heat-sealed Tyvek lid. The product is sterilized using ethylene oxide gas. Bacterial endotoxin levels are monitored for sterility release purposes.

F. CONCLUSION

Based on the information presented, Boston Scientific Corporation believes that the proposed low profile port meets the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently marketed vascular access port and catheter systems.