

K955587

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: 480 Pleasant Street
Watertown, MA 02172
(508) 850.8174

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, nutritional and the withdrawal of venous blood samples. The port kit, which is the subject of this premarket notification, provides procedural components necessary for percutaneous insertion of the implantable vascular access system.

C. DESCRIPTIVE CHARACTERISTICS

The port kit provides an implantable port and catheter, an introducer sheath/dilator with a hemostasis valve, a 22 Ga. non-coring needle, a 21 Ga. entry needle, a 20 Ga. blunt needle, and 0.018" and 0.035" guidewires. All of these components have been found substantially equivalent through the premarket notification process for the use(s) for which the port vascular assess kit is intended.

D. SUBSTANTIAL EQUIVALENCE

The proposed venous access port kit has been shown to be substantially equivalent to the individual devices sold individually and to other predicate vascular access port kits, such as Cook's VITAL-PORT MINI Vascular Access Port with Detached Catheter and Pharmacia Deltec's PORT-A-CATH Implantable Access System.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

Components comprising the kit are assembled in a PETG blister tray with a snap-fit lid. The tray is placed in a Tyvek/mylar pouch, which is then heat sealed. The kit 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 venous access port kit meets the minimum requirements that are considered acceptable for its intended use.