

Boston Scientific Corporation
January 10, 1996

JUN 21 1996

510(k) Premarket Notification
Percutaneous Introducer System

FOI RELEASABLE

K961219

510(K) Summary

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

Date: January 10, 1996

Owner Operator Submitting this Premarket Notification: Boston Scientific Corporation
480 Pleasant Street
Watertown, MA 02172
(508) 650-8000

Contact Person: Lorraine M. Hanley
Project Manager, Regulatory Affairs

Device Common Name: Percutaneous Introducer System

Device Trade Name: To be Determined

Classification Name: Boston Scientific Corporation believes that the Percutaneous Introducer System is best described by the following device classification names:

Catheter Introducer:
Class II, CFR 870.1340
Introducer/Drainage Catheter and Accessories
Class I, 21 CFR 878.4200

Device Description & Intended Use:

The kit is comprised of guidewire(s), access needles(s), dilator(s), drainage catheter with connecting tube, scalpel and syringe. The proposed kit is indicated for suprapubic bladder drainage and percutaneous access for the placement of thermosensor probes in patients undergoing ultrasound-guided urological cryosurgery procedures in accordance with the indications of legally marketed cryosurgery systems.

Substantial Equivalence:

All components of the proposed kit are either legally marketed preamendment devices, exempt from 510(k) Premarket Notification or have been found to be substantially equivalent through the 510(k) process for the uses for which the kit is intended.

Conclusions:

Based on the information presented in this current premarket notification, Boston Scientific Corporation believes that the proposed Percutaneous Introducer System is safe and effective, that it will meet the minimum requirements that are considered acceptable for its intended use, and that a determination of "substantial equivalence" is supported.