JAN 28 1997 K965067

p1 of 2

510 (k) Summary Of Safety And Effectiveness

Sponsor: Boston Scientific Corporation
One Scientific Place
Natick, MA 01760-1537

Contact Person: Carol J. Holloway
Regulatory Affairs Specialist

Submission Date: December 13, 1996

Common/Usual Names: Dilatation Catheter, Balloon

Trade/Proprietary Name: TBD

Classification Name: Boston Scientific Corporation believes the proposed device can be described by the following device classification names:

- Dilator, Catheter, Ureteral (78 EZN)
- Catheter, Urethral Dilator (78 KOE)
- Catheter, Balloon (79 GBA)
- Catheter, Dilator (79 GCC)

Device Classification: Boston Scientific Corporation believes the proposed device is classified as a Class II device under:

- 21 CFR 876.5470; Ureteral Dilator
- 21 CFR 876.5520; Urethral Dilator
- 21 CFR 878.4200; Introduction/Drainage Catheter
- 21 CFR 876.5130; Urological Catheter

K965067

p2 of 2

510 (k) Summary Of Safety And Effectiveness Continued

Description of Device:	The UDB Catheter is a combination over-the-wire, non-over-the -wire device. It consists of a two-lumen, catheter shaft with a molded bifurcation, a dilatation balloon and a Coudé tip. A 10 cc luer lock syringe is included in the tray.
Intended Uses:	The UDB Catheter is intended to dilate constricted areas of the urethra, prostatic urethra and ureters.
Substantial Equivalence:	The proposed devices are *Substantially Equivalent* to the predicate currently marketed devices indicated for use for dilatation of the urethra, prostatic urethra and ureters.
Product Testing:	The proposed devices have been tested and compared to the predicate devices. The results indicate that the proposed devices are *Substantially Equivalent* to the predicate devices in terms of performance characteristics tested.