

MAR 28 1997

K970053

P172

SECTION 9
510(K) SUMMARY

FOI RELEASABLE

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 6, 1997
 - COMMON/USUAL NAMES: Sphincterotome
 - TRADE/PROPRIETARY NAME: Unknown this time
 - CLASSIFICATION NAME &
DEVICE CLASSIFICATION: Class II
- | Name | Number | 21 CFR Ref. |
|---|--------|-------------|
| Endoscopic Electrosurgical
Unit and Accessories. | 78 KNS | 876.4300 |
- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Gastro-Renal (GRDB)
 - OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
 - CONTACT PERSON: Lisa M. Quaglia, Senior Regulatory Affairs Specialist

DESCRIPTION OF DEVICE

The Microvasive UltratomeRX is a triple lumen sphincterotome. The UltratomeRX is capable of accepting a .035" guidewire in one open channel while simultaneously injecting or cutting in another lumen. The open channel allows for the quick exchange of a guidewire completely isolated from injection agents and cutting. No stylet is necessary for scope passage.

INDICATIONS FOR USE

K970053

P202

The UltratomeRX is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Microvasive UltratomeRX can also be used to cannulate and inject contrast medium.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the UltratomeRX is substantially equivalent to the currently-marketed Boston Scientific Ultratome XL. The major components of the UltratomeRX are the catheter shaft, cutting wire, handle, guidewire introducer, and outer sheath. A thorough comparison of the descriptive characteristics between the UltratomeRX and the predicate device shows equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the UltratomeRX to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the UltratomeRX with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that UltratomeRX is substantially equivalent to the currently-marketed UltratomeXL. A comparison of the descriptive characteristics of these products demonstrate the UltratomeRX is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the UltratomeRX will meet the minimum requirements that are considered acceptable for its intended use.