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SECTION 9
510(K) SUMMARY

FEB 10 1997

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: Injection Cannula
- TRADE/PROPRIETARY NAME: Unknown at this Time
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class I

Name	Number	21 CFR Ref.
Cannula, Injection	79 FGY	KNS

- 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

The Microvasive TandemRX is a triple lumen ERCP cannula capable of accepting an .035" guidewire in one open channel while simultaneously injecting contrast media through the other two lumens. The two lumens are joined at the proximal end so that injection of contrast medium can be accomplished through a single injection port. The open channel allows for the quick exchange of a guidewire completely isolated from injection agents. No stylet is necessary for scope passage. The TandemRX may be placed with or without the aid of a guidewire.

INDICATIONS FOR USE

The TandemRX is indicated for use to cannulate and inject contrast media to obtain a cholangiogram of the biliary duct system. The contrast media is injected through the cannula and fluoroscopy or x-ray is performed to obtain the cholangiogram.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the TandemRX is substantially equivalent to the currently-marketed Microvasive Tandem XL Cannula. The major components of the TandemRX are the shaft, hub, guidewire introducer, and the outer sheath. A thorough comparison of the descriptive characteristics between the TandemRX and the predicate device shows equivalence.

PERFORMANCE CHARACTERISTICS

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

CONCLUSION

Boston Scientific Corporation believes that TandemRX is substantially equivalent to the currently-marketed Microvasive Tandem XL. The Modified TandemRX 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 TandemRX will meet the minimum requirements that are considered acceptable for its intended use.