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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: Endoscopic Biliary Stone Retrieval Balloon Catheter
- TRADE/PROPRIETARY NAME: Unknown at this Time
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Catheter, Biliary	78 FGE	876.5010

- 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 ExtractorRX is a triple lumen retrieval balloon catheter. The ExtractorRX is capable of accepting an .035" guidewire in one open channel while simultaneously injecting and/or inflating the balloon in the other two lumens. An open channel allows for the quick exchange of a guidewire completely isolated from injection agents and balloon inflation. No stylet is necessary for scope passage. The ExtractorRX may be placed with or without the aid of a guidewire.

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INDICATIONS FOR USE

The ExtractorRX is indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

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

PERFORMANCE CHARACTERISTICS

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

CONCLUSION

Boston Scientific Corporation believes that ExtractorRX is substantially equivalent to the currently-marketed Microvasive Extractor XL. A comparison of the descriptive characteristics of these products demonstrate the ExtractorRX 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 ExtractorRX will meet the minimum requirements that are considered acceptable for its intended use.