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SECTION 7  
510(K) SUMMARY

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**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.

- COMMON/USUAL NAMES: Hemorrhoidal Ligator, Esophageal Variceal Ligator
- TRADE/PROPRIETARY NAME: Speedband™ Multiple Band Ligator
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II
- CONTACT PERSON: Lisa M. Quaglia, Senior Regulatory Affairs Specialist

**INDICATIONS FOR USE**

The Speedband Multiple Band Ligator is indicated for endoscopic ligation of anorectal hemorrhoids and esophageal varicies.

**DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES**

Boston Scientific Corporation believes that the Modified Speedband™ is substantially equivalent to the currently-marketed Speedband™ and the Wilson Cook Six Shooter. These devices share similar materials, manufacturing process, and intended use. The major components of the Modified Speedband™ are the ligating handle and the ligating unit.

**PERFORMANCE CHARACTERISTICS**

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

**CONCLUSION**

Boston Scientific Corporation believes that Modified Speedband™ is substantially equivalent to the currently-marketed Speedband™ as well as the Wilson Cook Six Shooter. The Modified Speedband™ is equivalent in its indications for use, while being very similar in design and

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materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Speedband™ will meet the minimum requirements that are considered acceptable for its intended use.