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SECTION 9
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.

- DATE: January 22, 1997
- COMMON/USUAL NAMES: Endoscopic Electrosurgical Unit
- TRADE/PROPRIETARY NAME: Microvasive Gold Probe
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Unit, Electrosurgical	**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 Gold Probe and is a bipolar probe available in 7 Fr and 10 Fr. The catheter length is 217 - 350 cm long and is designed as circumactive probes which deliver effective electrocautery en fosse and tangentially. A central irrigation channel allows for site washing.

INDICATIONS FOR USE

The Gold Probe is indicated for use in transendoscopic electrocautery of visible bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus, stomach, duodenum, and colon. The indications include peptic ulcers, Mallory-Weiss tears,

arteriovenous malfunctions (AVMs), Dieulafoy lesions, bleeding polyp stocks, angiomata, Watermelon Stomach, Barrett's Esophagus, angiodysplasia, and esophageal tumors.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Gold Probe is substantially equivalent to the currently-marketed Microvasive Gold Probe and the ACMI Bicap Tumor Probe. The major components of the Gold Probe are the catheter shaft, the tip, and the irrigation port. A thorough comparison of the descriptive characteristics between the Gold Probe and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

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

CONCLUSION

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