K961349

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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.

- COMMON/USUAL NAMES: Electrohemostasis and Injection Therapy Catheter
- TRADE/PROPRIETARY NAME: Injection Gold Probe™
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class I/II/III

Name	Number	21 CFR Ref.
Unit, Electrosurgical, Endoscopic (with Accessories)	78 KNS	876.4300
Endoscope and/or Accessories	78 KOG	876.1500

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU) Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760, Owner/Operator No. 9912058
- CONTACT PERSON: Daniel J. Dillon, Senior Regulatory Affairs Specialist

INDICATIONS FOR USE

The Modified Injection Gold Probe and Injection Gold Probe Direct are indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following: peptic ulcers; Mallory-Weiss tears; arteriovenous malformations (AVMs); Dieulafoy lesions; bleeding polyp stocks; and angiomata. The Modified Injection Gold Probe and Injection Gold Probe Direct also have irrigation capability.

CONTRAINDICATIONS

Contraindications for this device are those specific to injection therapy and bipolar electrohemostasis treatments. These contraindications include, but are not limited to: non-focal bleeding sites; esophageal/gastric varices; diffuse lesions; allergies to injection agents.

POTENTIAL COMPLICATIONS

Possible complications include, but may not be limited to: perforation; bleeding, post-injection ulceration with delayed bleeding; aspiration pneumonia; pleural effusion; other respiratory difficulties; hepatic failure; septicemia/infection; chest pain; esophageal ulcers; esophageal strictures; dysphagia, fulguration, burns, stimulation and cardiac arrhythmias

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Injection Gold Probe is substantially equivalent to the currently-marketed Injection Gold Probe. Figure 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

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

PACKAGING, STERILIZATION, AND PYROGENICITY

The Modified Injection Gold Probe will be packaged in a styrene tray with a spun-bonded polyolefin lid. Modified Injection Gold Probe will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization. Pyrogenicity testing will be performed on a periodic basis to monitor bacterial endotoxin levels.

CONCLUSION

Boston Scientific Corporation believes that Modified Injection Gold Probe is substantially equivalent to the currently-marketed Modified Injection Gold Probe. Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1. the Modified Injection Gold Probe 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 Modified Injection Gold Probe will meet the minimum requirements that are considered acceptable for its intended use.

FIGURE 9-1: COMPARISON OF
MODIFIED INJECTION GOLD PROBE AND INJECTION GOLD PROBE

	Modified Injection Gold Probe (This 510(k))	*Injection Gold Probe (510(k) No. K942301)*
USE		
Indication	Endoscopic injection therapy and electrohemostasis of actual or potential bleeding sites in the gastrointestinal tract.	«— Same
Route of Administration	Endoscopic	«— Same
CATHETER SHAFT		
Usable Length	210 - 350 cm	«— Same
Shaft OD	7 - 10 F	«— Same
BIPOLAR HEMOSTASIS		
Bipolar Tip	Yes	«— Same
INJECTION THERAPY		
Needle Material	Stainless Steel	«— Same
Needle Gauge	25 Gauge	«— Same
Needle Extension Length	4 - 6 mm	«— Same
IRRIGATION CAPABILITY		
Irrigation Capability	Yes	«— Same