

SEP - 4 1996

SECTION 9
510(K) SUMMARYFOI 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: Tube, Gastro-Enterostomy
 - TRADE/PROPRIETARY NAME: Microvasive Balloon Gastrostomy Tube Kit
 - CLASSIFICATION NAME &
DEVICE CLASSIFICATION: Class II
- | | Name | Number | 21 CFR Ref. |
|--|--------------------------|-----------------------------------|-------------|
| | Tube, Gastro-Enterostomy | 78K ^{KNT} KOC | 876.5980 |
- 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, Regulatory Affairs Specialist

INDICATIONS FOR USE

The Balloon Gastrostomy Tube Kit is indicated for use in percutaneous placement of a gastrostomy tube for feeding and/or medication in conjunction with an established gastrostomy tract, or using a Stamm Procedure. The gastrostomy tube may also be used for gastric decompression

CONTRAINDICATIONS

Contraindications for this device are those specific to patients where evidence of granulation tissue, infection or stoma irritation are present. The product must NEVER be used in the vasculature.

POTENTIAL COMPLICATIONS

Complications may include, but are not limited to minor wound infections at stoma site; leakage of gastric contents; gastrocolic fistula; and sepsis.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Balloon Gastrostomy Tube Kit is substantially equivalent to the currently-marketed MRI All Silicone Gastrostomy Tube and Corpak Medsystems Corflo™-Dual GT Gastrostomy Tubes. Figure 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

The components of the Balloon Gastrostomy Tube Kit have the same characteristics as those devices that are currently marketed. There is no change in the performance characteristics or intended use.

PACKAGING, STERILIZATION, AND PYROGENICITY

The Balloon Gastrostomy Tube Kit will be packaged in a tray and sealed with a Tyvek lid. The Balloon Gastrostomy Tube Kit 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 the Balloon Gastrostomy Tube Kit is substantially equivalent to the currently-marketed devices. Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1, the Balloon Gastrostomy Tube Kit is equivalent in its indications for use, design, and materials.

FIGURE 9-1: SIMILARITIES AND DIFFERENCES BETWEEN BALLOON GASTROSTOMY TUBE KIT, MRI ALL SILICONE GASTROSTOMY TUBE, AND CORPAK MEDSYSTEMS CORFLOTM-DUAL GT GASTROSTOMY TUBES

	<i>Microvasive Balloon Gastrostomy Tube Kit (This 510(k))</i>	<i>MRI All Silicone Gastrostomy Tube (K951489)</i>	<i>Corpak Medsystems CorfloTM-Dual GT Gastrostomy Tubes (K901501)</i>
USE			
<i>Indication</i>	Feeding, medication, gastric decompression	Feeding, medication, gastric decompression	Feeding and medication
<i>Route of Administration</i>	Percutaneous	Percutaneous	Percutaneous
GASTROSTOMY TUBE			
<i>Material</i>	Silicone	Silicone	Silicone
<i>Length</i>	7-18"	7.5"	9"
<i>Diameter</i>	10 - 28 Fr.	12 - 28 Fr.	12 - 24 Fr.
KIT COMPONENTS			
<i>Gastrostomy Tube</i>	Yes	Yes	Yes
<i>Pre-Filled Syringe</i>	Yes	No	Yes
<i>Guidewire</i>	Yes	No	No
<i>Gauze</i>	Yes	No	Yes
<i>Drainage Sponge</i>	Yes	No	No
<i>Swabsticks</i>	Yes	No	No
<i>Lubricating Jelly</i>	Yes	No	Yes
<i>Antibiotic Ointment</i>	Yes	No	Yes
<i>Enteral Y Extension</i>	No	No	Yes