K963252

SEP 20 1996

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: Needle, Endoscopic
- TRADE/PROPRIETARY NAME: TBAN
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Needle, Endoscopic	78 FBK	876.1500

- 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 *Transbronchial Aspiration Needle* is indicated for use in aspiration in carinal, paratracheal, hilar, and peripheral lesions of the bronchial tree where biopsy forceps cannot obtain a submucosal sample.

CONTRAINDICATIONS

There are no known contraindications with this device.

POTENTIAL COMPLICATIONS

Possible complications include, but may not be limited to, inadvertent perforation of the bronchial tree.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Transbronchial Aspiration Needle is substantially equivalent to the currently-marketed Boston Scientific's TBAN and Mill Rose's Transbronchial Aspiration Needles. Figure 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

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

PACKAGING, STERILIZATION, AND PYROGENICITY

The Modified Transbronchial Aspiration Needle will be packaged in a pouch. The Modified Transbronchial Aspiration Needle 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 its Modified Transbronchial Aspiration Needle is substantially equivalent to the currently-marketed Boston Scientific Transbronchial Aspiration Needle and the Mill-Rose Transbronchial Aspiration Needle. Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1, the Modified Transbronchial Aspiration Needle 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 Transbronchial Aspiration Needle will meet the minimum requirements that are considered acceptable for its intended use.

FIGURE 9-1: SIMILARITIES AND DIFFERENCES BETWEEN MODIFIED TRANSBRONCHIAL ASPIRATION NEEDLE, BOSTON SCIENTIFIC'S TBAN, AND MILL-ROSE'S TRANSBRONCHIAL ASPIRATION NEEDLE

	Modified Transbronchial Aspiration Needle *(This 510(k))*	*Boston Scientific's TBAN* (K840033)	*Mill-Rose's Transbronchial Aspiration Needle* *(K914181)*
USE			
Indication	Aspiration in carinal, hilar, paratracheal, and peripheral lesions	Aspriation	Aspiration for cytology/histology
Route of Administration	Bronchoscope	Bronchoscope	Bronchoscope
DESIGN FEATURES			
Cross Section	Double Lumen	Double Lumen	Single or double Lumen
Retractable Needle	Yes	Yes	Yes
DIMENSIONS			
Catheter Length (cm)	150	150	140
Outer Catheter OD	1.8	1.8	1.8
Needle Size (Ga)	18, 19, & 21	18 & 21	19 - 22
Needle Length (mm)	14 & 20	13 & 20	13 & 15