

SECTION 9  
510(K) SUMMARY

NOV 10 1997

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: Balloon Catheter
- > TRADE/PROPRIETARY NAME: Olbert Balloon Catheter System®, NoProfile® Olbert Balloon Catheter System®

- > CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Esophageal Dilator	78 KNQ	876.5365
Endoscope & Accessories	78 KOG	878.1500

- > 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 Olbert® Balloon Catheter products are recommended for biliary tract stenosis/sphincter stenosis and gastrointestinal tract dilatation through a flexible endoscope. The recommended application is printed on the label.

CONTRAINDICATIONS

Not recommended for cases in which the bile duct has been surgically intervened, a stricture which is totally impassable, or for dilatation of strictures due to external mechanical obstruction, i.e., suture and metallic clips.

### POTENTIAL COMPLICATIONS

Potential complications with biliary tract dilation include intra-hepatic ductal damage, transient bleeding, post-operative cholangitis, and stricture of a primary hepatic duct. Potential complication from GI tract dilation include, but may not be limited to perforation, hemorrhage, hematoma, septicemia./infection, allergic reaction to contrast medium.

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

Boston Scientific Corporation believes that the Modified Olbert® Balloon Catheter is substantially equivalent to the currently-marketed predicate devices. Table 9-1 compares the descriptive characteristics of these products.

### PERFORMANCE CHARACTERISTICS

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

### PACKAGING, STERILIZATION, AND PYROGENICITY

The Modified Olbert® Balloon Catheter will be packaged a styrene/butadiene copolymer (SBS) tray with a Tyvek lid and a Tyvek outer pouch. The Modified Olbert® Balloon Catheter 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 Olbert® Balloon Catheter is substantially equivalent to the currently-marketed predicate devices. Table 9-1 compares the descriptive characteristics of these products. As demonstrated in Table 9-1, the Modified Olbert® Balloon Catheter 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 Olbert® Balloon Catheter will meet the minimum requirements that are considered acceptable for its intended use.

TABLE 9-1: COMPARISON OF MODIFIED OLBERT® BALLOON CATHETER TO PREDICATE DEVICES

	Modified Olbert® Balloon Catheter (This 510(k))	NoProfile® with Modified End Connector (510(k) No. K934411)	Modified NoProfile® (510(k) No. K945576)	NoProfile® with Vectran Fibers (510(k) No. K952887)	Olbert Balloon Catheter for Biliary Dilatation (510(k) No. K851647)	Vector TTS™ Balloon Dilatation Catheter (510(k) No. K961438)
--	---	---	---	---	---	--

USE

Indication	Dilatation of Biliary and Other Non-GI Strictures	«— Same	«— Same	«— Same	«— Same	Dilatation of GI Strictures
------------	--	---------	---------	---------	---------	--------------------------------

BALLOON

	4 - 14 mm	3 - 10 mm	3 - 10 mm	3 - 12 mm	4 - 14 mm	6 - 25 mm
Diameter	2.5 - 4.0 cm	2.0 - 4.0 cm	2 - 10 cm	2 - 10 cm	2.5 - 4.0 cm	5.5 - 8.0 cm
Length	9 - 12 atm	10 - 12 atm	10 - 12 atm	12 atm	9 - 12 atm	2 - 6 atm
Maximum Recommended Pressure	Polyurethane	«— Same	«— Same	«— Same	«— Same	Ethylene Vinyl Acetate
Material						

CATHETER SHAFT

	180 cm	180	40 - 180 cm	40 - 180 cm	40 - 180 cm	180 - 240 cm
Length	5.8 - 7.8 Fr	4.8 - 7.8 Fr	4.8 - 7.8 Fr	4.8 - 7.8 Fr	6 - 7.5 Fr	7 Fr., tapers to 5 Fr
Diameter						

350 9389

5-1-5115  
3 of 3



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

March 25, 2015

Boston Scientific Corporation  
Daniel J. Dillon  
Senior Regulatory Affairs Specialist  
One Boston Scientific Place  
Natick, MA 01760-1537

Re: K973113  
Trade/Device Name: Olbert Balloon Catheter System®  
Regulation Number: 21 CFR§ 876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: FGE, KNQ  
Dated (Date on orig SE ltr): August 18, 1997  
Received (Date on orig SE ltr): August 20, 1997

Dear Daniel J. Dillon,

This letter corrects our substantially equivalent letter of November 10, 1997.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joyce M. Whang -S**

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

SECTION 1  
INDICATIONS FOR USE

---

510(k) Number: K973113

Device Name: Modified Olbert® Balloon Catheter

Indication for Use:

The Modified Olbert® Balloon Catheter products are recommended for biliary tract stenosis/sphincter stenosis and gastrointestinal tract dilatation through a flexible endoscope. The recommended application is printed on the label.\*

- \* The recommended application on the label may refer to any combination of transpapillary, pyloric, colonic, anastomotic, and/or esophageal dilatation.

Robert P. Rathin  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K973113

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_