

Traditional 510(k)

K133439 Pilling® Esophageal Bougies

Refuse to Accept Response: Section 5 – 510(k) Summary

510(k) SUMMARY

JUN 16 2014

Pilling® Esophageal Bougies**A. Name, Address, Phone, and Fax Number of Applicant**

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4918
Fax: 919-433-4996

B. Contact Person

Holly Kornegay
Regulatory Affairs Specialist

C. Date Prepared

April 11, 2014

D. Device Name

Trade Name:	Pilling® Esophageal Bougies
Common Name:	Esophageal Bougie
Classification Regulation:	CFR 876.5365
Classification:	Class II
Panel:	Gastroenterology/Urology
Product Code:	FAT
Classification Name:	Esophageal Dilator

E. Device Description

Pilling® Esophageal Bougies are weighted, cylindrical instruments used for the dilation of the larynx and esophagus. They are designed to be reusable and re-sterilized by the user. Made from silicone elastomer and filled with tungsten, the bougies are marketed in French sizes 20 to 60. Pilling® Bougies have two tip styles; the Maloney bougie has a long tapered tip and the Hurst has a rounded tip. Both tips

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are impregnated with radio-opaque material (barium sulfate) and contain calibration marks along the tubing. By inserting the bougie through the patient's mouth and down the patient's esophagus, a clinician can mechanically push a blockage out of the esophagus or can mechanically dilate a stricture in the esophagus.

F. Indications for Use

The Pilling® Esophageal Bougies are indicated for the dilation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures and temporary ease of esophageal carcinoma.

G. Contraindications

Contraindications include those specific to upper GI endoscopy. Contraindications to dilation include, but are not limited to: asymptomatic strictures; coagulopathy; known or suspected perforation; severe inflammation or scarring near the dilation site, recent myocardial infarction, active ulcer and severe cervical arthritis.

H. Substantial Equivalence

The proposed Pilling® Esophageal Bougies are substantially equivalent to the predicate reusable esophageal dilation devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Medovations® M-Flex™ Esophageal Bougies	Medovations, Inc.	K972119	02/02/1998

I. Comparison to Predicate Devices

The proposed Pilling® Esophageal Bougies have the same technology, indications for use and functional characteristics as the predicate system that has been cleared under Medovations, Inc.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Pilling® Esophageal Bougies and the predicate has been performed. The results of this comparison demonstrate that the esophageal bougies utilize the same technology as the predicate device. A summary of these comparisons is included in the table below. For a complete comparison chart, please refer to Section 16.

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Technological Characteristics	Predicate Device, Medovations® M-Flex™ Esophageal Bougies	Proposed Device, Pilling® Esophageal Bougies	Comparison
Indications for Use	For dilation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures, and temporary ease of esophageal carcinoma.	The Pilling® Esophageal Bougies are indicated for the dilation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures and temporary ease of esophageal carcinoma.	Same
Contraindications	Contraindications include those specific to upper GI endoscopy. Contraindications to dilation include, but are not limited to: uncooperative patient; asymptomatic strictures; inability to advance the bougie through the strictured area; coagulopathy; known or suspected perforation; severe inflammation or scarring near the dilation site, recent myocardial infarction, active ulcer and severe cervical arthritis.	Contraindications include those specific to upper GI endoscopy. Contraindications to dilation include, but are not limited to: asymptomatic strictures; coagulopathy; known or suspected perforation; severe inflammation or scarring near the dilation site, recent myocardial infarction, active ulcer and severe cervical arthritis.	Upon careful review, Teleflex Medical, Inc. has determined that uncooperative patients and the inability for a physician to advance the bougie through a strictured area are not contraindications of the proposed device.
Tip Design	Maloney (tapered) and Hurst (blunt)	Maloney (tapered) and Hurst (blunt)	Same
Material	Silicone	70 and 80 durometer base silicone	Same
Bougie Colorant	Blue	Blue	Same
Weighting Mechanism	Tungsten-filled	Tungsten-filled	Same
Mercury-free	Yes	Yes	Same
Sizes (Diameter)	20FR to 60FR	20FR to 60FR	Same
Depth Markings	American and European	American and European	Same

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L. Performance Data

Teleflex has performed bench testing on both devices to verify that the performance of the proposed Pilling® Esophageal Bougies are substantially equivalent to that of the predicate bougies and that the Pilling® Esophageal Bougies are seamlessly interchangeable with the predicate bougies. Tensile tests were performed to simulate the process of the end-user manually removing the bougies from a patient’s esophagus. All samples of both products met the pre-defined acceptance criteria, which supports the substantial equivalence claim that these two devices are functionally equivalent.

The test results, which are summarized below, conclude that the Pilling® Esophageal Bougies’ performance is equivalent to the Medovations® M-Flex™ Esophageal Bougies’ performance.

Product Description	Quantity	Test Parameters	Results
Pilling® Hurst Tungsten-filled Bougie (20Fr)	30 samples	The tensile strength between the bougie plug and casing shall be at least 10 lbs.	All 30 samples passed the performance test. The Pilling® Esophageal Bougies have a tensile strength of at least 10 lbs. Avg 20.49 lbs. Min 14.24 lbs. Max 22.76 lbs.
Medovations® M-Flex™ Hurst Tungsten-filled Bougie (20Fr)	30 samples	The tensile strength between the bougie plug and casing shall be at least 10 lbs.	All 30 samples passed the performance test. The Medovations® M-Flex™ Esophageal Bougies have a tensile strength of at least 10 lbs. Avg 14.92 lbs. Min 10.83 lbs. Max 26.83 lbs.

L. Conclusion

Based upon the comparative test results, the proposed Pilling® Esophageal Bougies are substantially equivalent in performance to the predicate devices cleared to market via 510(k) K972119. The new design of the Pilling® Esophageal Bougies does not introduce any new issues of safety and effectiveness.



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

June 16, 2014

Teleflex Medical, Inc.
Holly Kornegay
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K133439
Trade/Device Name: Pilling® Esophageal Bougies
Regulation Number: 21 CFR§ 876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: FAT
Dated: April 11, 2014
Received: April 17, 2014

Dear Holly Kornegay,

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Benjamin R. Fisher -S

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

Indications for Use

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Device Name: Pilling® Esophageal Bougies

Indications for Use:

The Pilling® Esophageal Bougies are indicated for the dilation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures and temporary ease of esophageal carcinoma.

Prescription Use **XX**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin P. Fisher -S
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