K093325

Section 5 – 510(k) Summary

FEB 16 2010

General Information

Owner's Name:	N.M. Beale Co., Inc.
Address:	P.O. Box 494 Harvard, MA 01451
Telephone Number:	(800) 989-9558
Contact Person:	Nathaniel Beale, President
Subject Device:	
Trade Name:	Scope Introducer
Classification/Regulation:	KOG – Endoscope and/or accessories 21 CFR 876.1500; Class II
Predicate Devices:	
Trade Name:	Scope Introducer (Hobbs Medical, Inc)
Classification/Regulation:	KOG – Endoscope and/or accessories 21 CFR 876.1500; Class II
Premarket Notification:	Unknown

Device Description
The N.M. Beale Co., Inc. Scope Introducer consists of a one-piece metal construct with a luer fitting on one end and a tubular opening at the other end. The luer connector of the introducer can be connected to an irrigation source; the tubular end is inserted into the endoscope working channel to facilitate the introduction of accessories and/or irrigation. The Scope Introducer can be reused and is intended to be sterilized between uses.

Indications for Use
For use as an adapter for the introduction of tools and/or irrigation fluid through the endoscope working channel.

Performance Testing
Performance data provided in this submission consists of cleaning and sterilization validations.

Conclusion
The N.M. Beale Co., Inc. Scope Introducer is substantially equivalent to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 1 6 2010

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

N.M. Beale Co., Inc.
% Ms. Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K093329
Trade/Device Name: Scope Introducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: October 7, 2009
Received: November 30, 2009

Dear Ms. Papineau:

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.

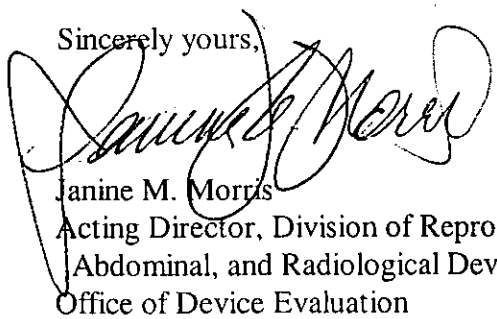
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K093329

Device Name: Scope Introducer

Indications for Use:

For use as an adapter for the introduction of tools and/or irrigation fluid through the endoscope working channel.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-the -Counter Use ____ (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093329