



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

December 15, 2015

Fujifilm Medical Systems USA, Inc.
Aaron Ge
RA Manager, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, New Jersey 07470

Re: K153483
Trade/Device Name: Balloon Controller PB-30
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDF, FDA
Dated: November 30, 2015
Received: December 3, 2015

Dear Aaron Ge:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,


Herbert P. Lerner -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

Indications for Use

510(k) Number (if known)

K153483

Device Name

Balloon Controller PB-30

Indications for Use (Describe)

This product is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over tube insertion. This product is not intended for use for any neonates, infants or children.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Fujifilm's Balloon Controller PB-30

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

Aaron Ge
Regulatory Manager, Regulatory Affairs and Quality Assurance
Telephone: (973) 686-2636 Ext. 522636
Facsimile: (973) 633-8818
E-Mail age@fujifilm.com

Date Prepared: November 30, 2015

Identification of the Subject Device:

Proprietary/Trade Name:	PB-30
Common Name:	Balloon Controller
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Colonoscope and Accessories (Flexible/Rigid), 21 C.F.R. § 876.1500
Product Code: FDF, FDA

Primary Predicate

Fujifilm Balloon Controller PB-20 (K143556)

Purpose of the Special 510(k) notice.

The PB-30 is a modification to PB-20.

Intended Use

This product is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over tube insertion. This product is not intended for use for any neonates, infants or children.

Technological Characteristics

The Fujifilm Balloon Controller PB-30 is a modified version of the legally marketed Fujifilm Balloon Controller PB-20 in K143556. Just like K143556, the proposed PB-30 is a balloon pump apparatus intended to inflate or deflate a balloon to assist with endoscope and over tube insertion. This product is not intended for use for any neonates, infants or children.

PB-30 is connected to the over-tube and double balloon endoscope via a tube kit. PB-30 feeds /evacuates air to the balloon of over-tube and to the balloon at the tip of the endoscope. All of the PB-30's accessories are legally marketed in the US.

Performance Data

Fujifilm conducted the following performance testing of the PB-30 to ensure that the modified device performs equivalently to the predicate PB-20:

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: ANSI/AAMI ES60601-1:2005; IEC 60601-1-2:2007; IEC 60601-1-6:2010; and IEC 60601-2-18:2009.

In all cases, the device met the pre-defined acceptance criteria for the test.

Substantial Equivalence

PB-30 has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate PB-20. The minor differences in the modified device's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the PB-30 is as safe and effective as PB-20. Thus, the PB-30 is substantially equivalent to its predicate device.