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K931896

LAFAYETTE

510(K) SUMMARY

Submitted By: Lafayette Pharmaceuticals Incorporated
522 N. Earl Avenue; P.O. Box
Lafayette, IN 47903

Contact Person: Robert A. Sharp, Technical Director
Telephone Number: (317) 447-3129

Trade Name: Pro-Flo System™
Common or Usual Name: Barium & Air Flow Remote Control Device for Fluoroscopy
Classification Name: Not Known

The Pro-Flo System is a remote control device used to control the flow rate of barium sulfate suspension and of air during air contrast x-ray examinations of the lower gastrointestinal tract. The Pro-Flo System is substantially equivalent to the E-Z-EM BariFlow Model #880 and PerfectView Model #6201 units currently on the market.

Air contrast x-ray examination of the lower gastrointestinal tract requires the rectal administration of barium sulfate suspension, typically 500 ml to 2000 ml, via an enema kit and air contrast enema tip. Following barium sulfate suspension administration, air is introduced through the air contrast enema tip. The use of a remote control device allows the radiologist to control the flow of barium sulfate suspension and air from the control room rather than tableside thus providing an added degree of safety for the radiologist and the technicians from radiation exposure during the examination. If a flow control device is not used, the radiologist and/or technologist would do the administration tableside.

The Pro-Flo System operates in substantially the same manner as the currently marketed units referred to above. The Pro-Flo System differs in that a battery operated wireless remote control is used. The Pro-Flo unit also incorporates a small medical air pump for the administration of air rather than the manual hand pump used for the E-Z-EM unit.

Simulation tests equivalent to three years use (7800 total tests) were performed on ten units. No electronic circuit or vice problems developed. A total of 3 light bulbs burned out, 1 on-off switch had to be replaced and 1 air pump gave 8% less air than normal. Use by radiologists confirmed the efficacy of the Pro-Flo System. One doctor reported using the unit for three months without any problems and stated that he preferred the Pro-Flo System to the other units on the market that he had tried.

The test results and evaluations of the Pro-Flo System show that it is safe, effective and substantially equivalent to currently marketed units used for flow control during air contrast x-ray examinations of the lower gastrointestinal tract using barium sulfate suspension.

Prepared: April 1, 1993

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Robert A. Sharp
Technical Director
Lafayette Pharmaceuticals Inc.
P.O. Box 4499
LAFAYETTE IN 47903

OCT 13 2012

Re: K931896A
Trade/Device Name: Pro-Flo System
Regulation Number: 21 CFR 876.5210
Regulation Name: Enema kit
Regulatory Class: I
Product Code: FCE
Dated: April 1 and August 18, 1993
Received: April 15 and August 20, 1993

Dear Mr. Sharp:

This letter corrects our substantially equivalent letter of August 26, 1993.

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 (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.

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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health