JUL 16 2014
K140558

510(K) SUMMARY

5.1 Submitter Information

A.	Company Name:	Access Pharmaceuticals, Inc.
B.	Company Address:	1325 Avenue of the Americas, 27th Floor New York, NY 10019
C.	Company Phone:	(212) 786-6205
D.	Company Facsimile:	(212) 786-6210
E.	Contact Person:	Jeffrey B. Davis President & CEO jeff.davis@accesspharma.com

5.2 Device Identification

A.	Device Trade Name:	ProctiGard™
B.	Common Name:	Protective coating, mucoadhesive application, for the rectal mucosa
C.	Classification Name:	Unclassified
D.	Device Class:	Unclassified
E.	Device Code:	PHN
F.	Advisory Panel:	Gastroenterology-urology

5.3 Identification of Predicate Devices

The liquid hydrogel formulation of ProctiGard™ is identical to that of MuGard®, and therefore ProctiGard™ is substantially equivalent to the following predicate device:

- MuGard® Mucoadhesive Oral Wound Dressing manufactured by Access Pharmaceuticals, Inc. and cleared for commercial distribution under 510(k) K062795.

5.4 Device Description

ProctiGard™ is a viscous, mucoadhesive liquid supplied in plastic bottles and is designed for the symptomatic management of rectal mucositis. When gently applied via the enema bottle applicator, the mucoadhesive formulation results in the formation of a protective coating over the rectal mucosa.

5.5 Indications for Use

ProctiGard™ is indicated for the symptomatic management of rectal mucositis.

5.6 Comparison to Predicate Devices

The liquid hydrogel formulation of ProctiGard™ is identical to that of MuGard® Mucoadhesive Oral Wound Rinse (Access Pharmaceuticals, Inc.) and similar to other legally marketed hydrogel wound dressing products. ProctiGard™ is designed for the rectal mucosa while MuGard® targets the oral mucosa. MuGard® is provided in an 8 fluid ounce bottle while ProctiGard™ is provided in a single use enema bottle.

The mode of action of ProctiGard™ is achieved in an identical manner to that of MuGard® Mucoadhesive Oral Wound Rinse, i.e., through the formation of a protective layer over the mucosa (over the rectal mucosa rather than the oral mucosa).

The composition of the liquid hydrogel of ProctiGard™ is identical to that of MuGard® Mucoadhesive Oral Wound Rinse, i.e., a mixture of film-forming polymers, pharmaceutical aids, and preservatives.

The safety of ProctiGard™ has been established through biocompatibility testing of the hydrogel liquid according to ISO 10993, i.e., *in vitro* cytotoxicity tests, sensitization testing in guinea pigs and mucosal irritation testing in rabbits.

On the basis of this information, Access Pharmaceuticals concluded that ProctiGard™ is safe and effective for its intended use and performs equivalently to the identified legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 16, 2014

Access Pharmaceuticals, Inc.
Jeffrey B. Davis
President & CEO
1325 Avenue of the Americas, 27th Floor
New York, NY 10019

Re: K140558
Trade/Device Name: ProctiGard™
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: PHN
Dated: June 12, 2014
Received: June 13, 2014

Dear Jeffrey B. Davis,

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, 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: K140558

Device Name: ProctiGard™

Indications for Use:

ProctiGard™ is indicated for the symptomatic management of rectal mucositis.

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

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Benjamin R. Fisher -S
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