



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

August 10, 2016

Colonplus Equipments & Speculums, S.L.
% Solmarie Rivera
Senior Medical Device Expert
Business Excellence Consulting, Inc.
City View Plaza Suite #802/ #48 Road 165 Km 1.2
Guaynabo, 00968 PR

Re: K152834
Trade/Device Name: Colonplus Colonkit Small / Colonplus Colonkit Large / Colonplus
Colonkit Large with Stop Collar 6 / Colonplus Colonkit Large
with Stop Collar 10
Regulation Number: 21 CFR§ 876.5220
Regulation Name: Colonic Irrigation System
Regulatory Class: II
Product Code: KPL
Dated: June 29, 2016
Received: June 29, 2016

Dear Solmarie Rivera:

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,

Douglas Silverstein -S

2016.08.10 11:24:57

-04'00'

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)
K152834

Device Name
Colonplus Colonkit Small / Colonplus Colonkit Large / Colonplus Colonkit Large with Stop Collar 6 / Colonplus Colonkit Large with Stop Collar 10

Indications for Use (Describe)
The device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

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."

5. 510(k) Summary

510(k) Owner's Name: Colonplus Equipments & Speculums, S.L.
Address: C/Portuetxe 13, 1-C
20.018 - San Sebastian (Guipuzcoa)
Spain
Phone: +34 670556449
Email: jorge@colonplus.net
Website: www.colonplus.net
Name of Contact Person: Jorge Echevarría
Address/Contact: C/Portuetxe 13, 1-C
20.018 - San Sebastian
Spain
Date Prepared: May 4, 2015
Trade Name: Colonplus Colonkit Small, Colonplus Colonkit Large, Colonplus Colonkit Large with Stop Collar 6, and Colonplus Colonkit Large with Stop Collar 10
Common Name: Colonic Irrigation System
Classification Name: System, Irrigation, Colonic (per 21 CFR 876.5220) Class II
Product Code: KPL
Predicate Devices: **Submission #: K050112**
Trade Name: Pro-Fit™ Disposable Speculum (Regular and Small Size)
Submission #: K131852 - Hydrokit
Trade Name: Transcom Colon Hydrotherapy Models HC-1 and HC-1 Classic And Hydrokit

Legally Marketed Devices to Which your Firm is Claiming Equivalence: The Colonplus Colonkits (Small, Large, Large with Stop Collar 6 and Large with Stop Collar 10) are substantially equivalent in intended use, indications for use, and design to the Prime Pacific Health Innovations Corporation Pro-Fit™ disposable speculum (Regular and Small size) cleared on March 15, 2005 under Pre-market Notification 510(k) number K050112. In addition, it is substantially equivalent in intended use, indications, design, and materials to the Hydrokit from Transcendencias Comerciales, S.L cleared on April 17, 2014 under Pre-Market Notification 510(k) K131852.

Description of the Device: The disposable rectal speculum is a non-metal (Polypropylene) device used to introduce water into the colon and dispose waste from the colon during a colonic irrigation procedure.

Intended Use of the Device: The device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

Technological Characteristics Compared to Predicate Device:

The Colonplus Colonkits have the same technological characteristics as, and are substantially equivalent to the Pro-Fit™ Disposable Speculums (K050112), manufactured by Prime Pacific Health Innovations Corporation (See Figure 5A, 5B, and 5C). Both products are to be used with colon hydrotherapy equipment. The Colonplus Colonkit large was designed with two variations including a stop collar (insertion stopper) with an irrigation water entrance with diameter of 6 mm and 10 mm, respectively. The Pro-Fit™ speculum, released per 510(k) K050112, was designed with an insertion stopper to avoid over insertion, as well. The design of the Colonplus Colonkit cannula with obturator is also substantially equivalent to the speculum in the Hydrokit predicate with Pre-market Notification 510(k) K131852. Both have models with and without stop collar. Refer to Figures 5D and 5E below.



Figure 5A Predicate Pro-Fit™ Disposable Speculum (with stop collar/limit)

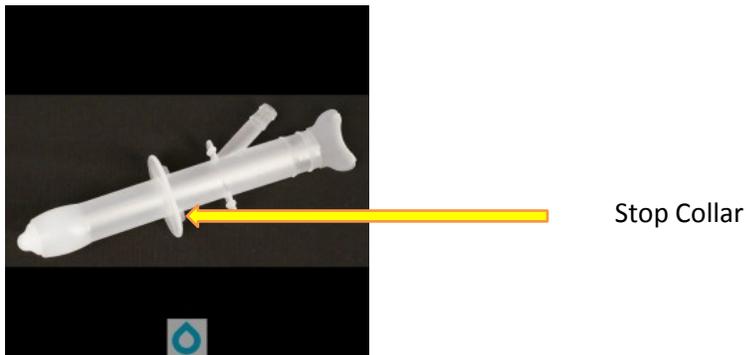


Figure 5B Colonplus Colonkit (cannula with stop collar)



Figure 5C Colonplus Colonkit (cannula without stop collar)



Figure 5D Polypropylene Predicate Hydrokit (cannula without stop collar)

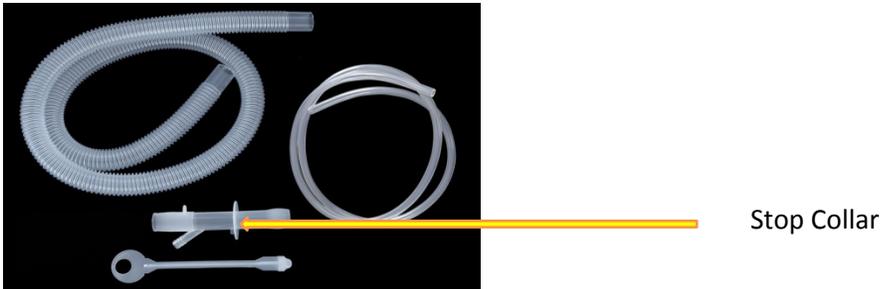


Figure 5E Polypropylene Predicate Hydrokit (kit including cannula with stop collar)

The Colonplus Colonkit cannula and obturator are made out of polypropylene, in contrast to the ProFit™ which is made out of polyethylene. Polypropylene has good impact strength, surface hardness, dimensional stability and excellent abrasion resistance. The finished colonkit was tested for biocompatibility by Laboratorio BIOLAB S.L in Spain. When compared with predicate 510(k) K131852 Hydrokit from Transcendencias Comerciales S.L, both are made out of polypropylene and have the same intended use and indications for use, which supports the substantial equivalence of materials.

The kit components of the Colonplus Colonkits (irrigation tube and evacuation tube) are also substantially equivalent to those included in the ProFit™ disposable speculum kit (water line and

water hose) manufactured by Prime Pacific Health Innovations Company through 510(k) K050112.

Indications for use

The device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Colonplus Colonkit System is supported by a comparison of the intended use, indications for use, and design with the Pro-fit™(K050112) and by a comparison of the intended use, indications for use, design and materials to the Hydrokit (K131852), as well as acceptable results from biocompatibility test.