K050112

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510(k) Summary

Submitted by: Prime Pacific Health Innovations Corporation
8 - 145 Riverside Drive
North Vancouver, BC
V7H 1T6
Canada
Tel: (604) 929-7143

Contact Person: Delmar Vogel

Date Prepared: November 25, 2004

Proprietary Name: Pro-Fit™ Disposable Speculum (Regular and Small Size)

Common Name: Disposable Rectal Speculum

Classification Name: System, Irrigation, Colonic (per 21 CFR section 876.5220)

Predicate Devices: Clearwater Colon Hydrotherapy, Inc. Disposable Speculum
Specialty Health Products Inc. Disposable Speculum
Dotolo Research Corp. Disposable Speculum

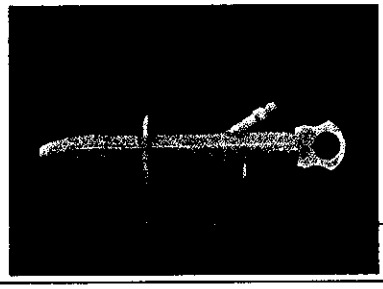
Description of Device: The Pro-Fit™ disposable rectal speculum is a non-metal (Polyethelene) device used to introduce water into the colon and dispose waste from the colon during a colonic irrigation procedure.

Intended use of the Device: To be used for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

Technical Characteristics: The Pro-Fit™ disposable speculums have the same technological characteristics as, and are substantially equivalent to the SP01 and SP02 disposable speculums (K000388), manufactured by Clearwater Colon Hydrotherapy Inc. The only difference is the insertion stopper present on the Pro-Fit™ Disposable Speculum.

The material used to manufacture the speculum & obturator is Fortiflex® HDPE T50-2000 polyethylene copolymer which meets FDA requirements 21CFR 177.1520. The finished Pro-Fit™ Speculum was tested for biocompatibility by North American Science Associates, Inc. (NAMSA).

Kit components packaged with the Pro-Fit™ disposable speculum (water line, waste hose, & surgical lubricant) are substantially equivalent to those included with the SP01 and SP02 disposable speculums, manufactured by Clearwater Colon Hydrotherapy Inc. and the other predicate device manufacturers.



Pro Fit Disposable Speculum with Insertion Stopper.

Clearwater Disposable Speculum.

K050112

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Indications for Use

510(k) Number (if known): _____

Device Name: Pro Fit Disposable Rectal Speculum, Regular and Small Size

Indications for Use:

"The indication for use of this device must be restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination."

Prescription Use _X_____ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2005

Mr. Delmar Vogel
President
Prime Pacific Health Innovations Corporation
8-145 Riverside Drive
North Vancouver, B.C.
CANADA V7H 1T6

Re: K050112
Trade/Device Name: Pro-Fit™ Disposable Speculum (Regular and Small Size)
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: 78 KPL
Dated: January 11, 2005
Received: January 18, 2005

Dear Mr. Vogel:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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); 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.

In addition, we have determined that your device kit contains sterile bacteriostatic surgical lubricant which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Pro Fit Disposable Rectal Speculum, Regular and Small Size

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AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050112