K052229

OCT 13 2006

510(k) Summary

Coloplast Ostomy Rod

1. Submitters name, address, phone and fax numbers
Coloplast Corp 1975 West Oak Circle Marietta, GA 30062 - 2249 U.S.A.
Tel.: (770) 281 8400 Fax: (770) 281 8500
2. Contact person at Coloplast Corp
Elizabeth Boots BA, MT Quality Assurance Vice President Coloplast Corp, Skin Care Division 1940 Commerce Drive P.O. Box 8300 N. Mankato, MN 56003 - 8300 U.S.A.
Tel.: (507) 386 4362 Cell: (507) 351 6750 Fax: (507) 345 3291 Email: usbb@coloplast.com
3. Date that the 510 (k) summary was prepared
September 29, 2006

4. Name of the medical device (trade, common and classification name)	
Trade name	**Coloplast** Ostomy Rod
Common Name	Loop Ostomy Rod
Classification name	Rod, Colostomy

5. Legally marketed device to which substantial equivalence is claimed

ConvaTec Sur-Fit System K811240

6. Description of the device

The **Coloplast** Ostomy Rod is a 90mm white HDPE rod with a fixed T at one end and a separate T piece that can be snapped into the open end of the rod once it is in place. Holes in the ends of the T allow for suturing. The device is packaged in a laminated polyethylene and gas-permeable paper pouch. The product is sterilized by irradiation.

7. Intended use of the device

Coloplast Ostomy Rod is used for loop ostomy surgery. The ostomy rod is a device that is placed through a loop of the colon brought out through the abdominal wall to temporarily keep it from slipping back through the surgical opening during the loop (colostomy or ileostomy) ostomy procedure.

8. Technological characteristics comparison to the predicate device

The ConvaTec Sur-Fit System has a size range of 65-90 mm that incluces the 90mm size for the **Coloplast** Ostomy Rod.

The ConvaTec Sur-Fit System has a fixed triangular shaped in a T at one end and an adjustable position triangular T at the other end to allow the T to be swiveled after insertion. It may be sutured through the triangular shapes, but does not need to be.

The **Coloplast** Ostomy Rod has a fixed T on one end a second T piece that can be snapped onto the opposite end of the rod once it is in place. It may be sutured through holes in the ends of the T arms, but does not need to be. Both are produced by injection molding.

The **Coloplast** Ostomy Rod and the ConvaTec Sure-Fit System are labeled as sterile by irradiation and for single use only.

Flexural strength and flexibility were compared with results for the **Coloplast** Ostomy Rod and the Conva-Tec Sure-Fit System giving similar results both well above the estimated effect from the colon.

The **Coloplast** Ostomy Rod is made from HDPE. This is not the same material used for the ConvaTec Sure-Fit System, but is widely used in the medical industry and is shown to meet biocompatibility requirements.

9. Non-clinical performance data

The **Coloplast** Ostomy Rod has been tested for tensile strength, flexural strength, stability and the sterilization process is validated and monitored through ongoing testing.

The **Coloplast** Ostomy Rod has been tested for biocompatibility, cytotoxicity, irritation and sensitization as required by ISO 10993-01 Biological Evaluation of Medical Materials and FDA Blue Book Memorandum #G95-1 and all critieria for acceptance were met.

Leachable profiles were tested for two lots of ostomy rods one at baseline and one near expiration and there was no significant change associated with time.

10. Conclusion

The **Coloplast** Ostomy Rod is similar in size, construction and design to the ConvaTec Sur-Fit System. The intended uses and classifications are the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Elizabeth Boots
Vice President, Quality Assurance
Coloplast Corporation
1940 Commerce Drive
N MANKATO MN 56002-8300

OCT 13 2006

Re: K052229
Trade/Device Name: Coloplast Ostomy Rod, Model 12814
Regulation Number: 21 CFR §876.4270
Regulation Name: Colostomy rod
Regulatory Class: II
Product Code: EZP
Dated: September 29, 2006
Received: October 3, 2006

Dear Ms. Boots:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.

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 (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150
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

Statement of Indications for Use

510(k) Number (if known): Not known

Device Name: **Coloplast** Ostomy Rod

Indications for Use:

Coloplast Ostomy Rod is for use in loop ostomy surgery. The ostomy rod is a device that is placed through a loop of the colon brought out through the abdominal wall to temporarily keep it from slipping back through the surgical opening during the loop (colostomy) ostomy surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

David C. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052229