MAR 2 4 2004

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510(K) SUMMARY (Section E)

1.	Submitted by:	Tools for Surgery, LLC
2.	Address:	1339 Stony Brook Road Stony Brook, New York 11790
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5.	Contact Person	Arnold R. Leiboff, M.D.
6.	Date Summary Prepared:	January 6, 2004
7.	Device Trade Name:	Easy Loop
8.	Common Name:	Colostomy Rod or Loop Ostomy Rod
9.	Classification Name:	Rod, Colostomy

10. Substantial Equivalency is claimed against the following device: "Loop Ostomy Rod" manufactured by Convatec, a division of Bristol-Myers Squibb Co. of Skillman, NJ; 510(K) #K830945.

11. Description of the Device: The Easy Loop is constructed of an eight inch long x 0.28" diameter PVC flexible tubing, to which is bonded at each end a 1.45" long generally arrow-shaped slotted PVC coupling member whose shape allows easy passage through the mesentery for placement of the device while resisting unintended withdrawal , and whose shape and slots permit interlocking of the two ends of the device to form a closed loop around the exteriorized loop of bowel.

12. Intended use of the device: For use in loop ostomy abdominal surgery to prevent the exteriorized loop of bowel of any caliber (diameter) from retracting into the body. The device is used in conjunction with any of the commercially available wafer and pouch component ostomy appliances.

13. Safety and effectiveness of this device: This device has been successfully employed by Board Certified Colon and Rectal Surgeons and was found to be as safe and effective as the predicate device cited above. See tabulated comparisons (paragraph 14 below) to further validate this claim.

14. Summary comparing technological characteristics with the predicate device: Please find a tabulated comparison supporting that this device is substantially equivalent to the predicate device in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

Arnold R. Leiboff, M.D.
President
Tools for Surgery, LLC
1339 Stony Brook Road
Stony Brook, New York 11790

Re: K040110
Trade/Device Name: Easy Loop, Model #EZL-01
Regulation Number: 21 CFR 876.4270
Regulation Name: Colostomy rod
Regulatory Class: II
Product Code: EZP
Dated: January 6, 2004
Received: January 20, 2004

Dear Dr. Leiboff:

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 (PMA), 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040110

Device Name: Easy Loop, Model # EZL-01

Indications For Use:

The Easy Loop is indicated for use in abdominal surgical procedures generally referred to as loop ostomies, or more specifically referred to as loop ileostomy and loop colostomy, where a loop of bowel is pulled through an abdominal incision and retained outside the body. This device, which prevents the exteriorized loop of bowel from retracting back into the abdominal cavity, is used in conjunction with commercially available ostomy appliances which collect the evacuated feces.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040110