K103086

JUN - 7 2011

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10972
USA
Phone: (845) 365-8200
Fax: (845) 365-8201

Contact Person: Daniel Consaga

Date of Summary: September 23, 2010

Trade/Proprietary Name: Dynarex Intermittent Catheter

Classification Name: Urological Catheter and Accessories

Product Code: EZD

Intended Use:

The Dynarex Intermittent Catheter is intended for use in male, female, and pediatric patients (children, adolescents and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those who have a significant volume of residual urine following a natural bladder-voiding episode. The catheter should not be retained in the human body for more than 24 hours.

Device Description:

The Intermittent Catheter consists of a flexible PVC tube. One end of the tube has two holes (eyelets) punched into the tube. These eyelets allow urine to enter the tube and be drained from the bladder. A piece of PVC connector (drain funnel) is attached to the opposite end of the PVC tube.

Predicate Device:

Self Cath Catheter, 510(k) Number K100878, manufactured by Holtedam 1, 3050 Humlebaek, Denmark

Substantial Equivalence:

The Dynarex Intermittent Catheter provides effective bladder drainage, and its function and performance are similar to the predicate device, Self Cath Catheter, K100878, cleared on May 26, 2010, as presented in this 510(k)

Safety and Effectiveness of the device:

This device is as safe and effective as the predicate device cited above. This is better expressed in the Risk Analysis Report WL-E-19-12A, dated August 31, 2009.

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Summary comparing technological characteristics with other predicate device:
Dynarex Intermittent Catheter is similar in terms of intended use and technological characteristics to predicate devices. The device is substantially equivalent with respect to indications for use and other physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Please find below a tabulated comparison supporting that this device is substantially equivalent to the predicate device in commercial distribution.

TECHNOLOGICAL CHARACTERISTICS	Self Cath Catheter K100878	Dynarex Intermittent Catheter
Indications for use	Bladder drainage	Substantially Equivalent
Target Population	Male, Female & Pediatric (Neonates, infants, children, adolescents, and transitional adolescents)	Male, Female & Pediatric (children, adolescents, and transitional adolescents)
Materials	PVC	PVC
Biocompatibility	ISO 10993 Part 5 & 10 Cytotoxicity, Skin Irritation & Sensitization	ISO 10993 Part 5 & 10 Cytotoxicity, Skin Irritation & Sensitization
Physical Testing	ASTM 10555, Force to Break, ASTM F-623, Flow Rate	ASTM 10555, Force to Break, ASTM F-623, Flow Rate
Anatomical sites	Urethral	Urethral

Performance Summary:

FDA has not established special controls or performance standards for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Daniel Consaga
Quality Engineer, Regulatory Affairs
Dynarex Corporation
10 Glenshaw Street
ORANGEBURG NY 10962

JUN - 7 2011

Re: K103086
Trade/Device Name: Dynarex Intermittent Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: June 2, 2011
Received: June 3, 2011

Dear Mr. Consaga:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103086

Indications for Use

510(k) Number (if known): K103086

Device Name: Dynarex Intermittent Catheter

Indications for Use:

The Dynarex Intermittent Catheter is intended for use in male, female, and pediatric patients (children, adolescents and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those who have a significant volume of residual urine following a natural bladder-voiding episode. The catheter should not be retained in the human body for more than 24 hours.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103086