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510(k) Summary

Trade name	Classic™ Intermittent Catheter.
C.F.R Section Product Code:	21 CFR 876.5130. Urological catheter and accessories EZD
Manufacturer:	Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Regulatory Affairs Contact:	Christopher Watkins Quality Regulatory & Technical Director Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Telephone:	00 44 1443 471 593
Date Summary Prepared:	September 2013
Common Name:	Intermittent catheter
Classification:	Class 2
Predicative Devices	• BARD "Interglide" which was cleared for marketing by 510(k) No **K951260**. • Coloplast "Self Cath" which was cleared for marketing by 510k No **K100878**

OCT 11 2013

Description:

Classic™ Intermittent Catheter is a PVC plastic device that is intended to be inserted through urethra and into bladder of patient to allow drainage of urine. The Classic Intermittent catheter in pouch consists of a tube which is bonded onto a drainage funnel.

Classic™ Intermittent Catheter has a round polished finish tip to provide maximum comfort for user. Each catheter features two large eyelets in order to drain urine efficiently. Drainage eyelets cut-outs are smooth and rounded to minimize the risk of injury/discomfort when in use.

Classic™ Intermittent Catheters are available in:
Adult Male. Available in coudé tip or straight tip

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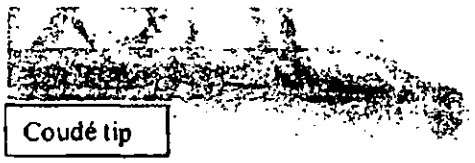
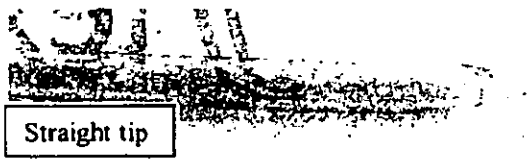
Adult Female. Available in straight tip
Paediatric. Available in straight tip


Coudé tip


Straight tip

Sizes are as follows:

French size	ID (mm)	OD (mm)	Total length
6	1.1	2.0	Male: 400mm Female: 160mm Paediatric: 240mm
8	1.7	2.7	
10	2.3	3.3	
12	2.8	4.0	
14	3.0	4.7	
16	3.6	5.3	
18	4.2	6.0	
20	4.7	6.7	

Intended Use:

Classic™ intermittent catheters are intended for use in male, female and paediatric patients when regular assisted bladder drainage has been instructed by a physician.
Classic™ intermittent catheters are indicated for use by individuals whose ability to void the bladder fully by natural bodily functions is impaired.

Substantial Equivalence

The Classic Intermittent Catheter has the same intended use as predicate devices:

- BARD "Interglide", which was cleared for marketing by 510k No K951260.
- Coloplast "Self Cath" which was cleared for marketing by 510k No K100878.

All three intermittent catheters are single patient use devices.
All three devices are not life supporting or life sustaining.

Only the Catheter Tube has invasive patient contact.
Patient Contact – Invasive – Limited Exposure (A)
Classification: Mucosal Membranes (B) | Limited (A).

All three intermittent catheters do not use software/ not electronically driven.
All three intermittent catheters are supplied sterile in individual peel pouches.

All three intermittent catheters are able to be used with accessories such as drainage bags, which are industry standard devices used with catheters.
All three intermittent catheters are designed for the same intended use in the same intended conditions.

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All three intermittent catheters consist of 2-3 components made from injection molded, sheet & extruded plastics.

From comparison testing it was determined that all invasive components of the three devices are manufactured from PVC. The connector of the Classic™ Intermittent Catheter and the Coloplast Self Cath are also manufactured from PVC, and have the same colour connector for each size.

The BARD Interglide catheter's connector is manufactured from TPE, however, TPE has similar characteristics to PVC (easily moulded, coloured, flexible, provides secure push fit connections, bonds easily with adhesives)
The Bard Interglide size 14 connector was green like the FML and Coloplast samples, however, other sizes were not available to compare colours.

All samples OD/ID's were very similar, within a range of ±0.2mm for each size. Full ID/OD details are recorded in TR079/12 Test report. (Section12).

Sample	Total length
FML male	400mm
FML female	160mm
FML peadiatric	240mm
Coloplast male	420mm
Coloplast female	Un-available
Coloplast paediatric	240mm
BARD male	355mm
BARD female	Un-available
BARD paediatric	Un-available

Summary of Testing: "Classic" intermittent catheter has been evaluated in accordance with:
BS EN 1616 - 1997 - Sterile Urethral Catheters for single use
BS EN 1618 - 1997 - Catheters other than intravascular catheters

Tests Performed:

Test	Standard? / In-House?	Outcome?
Visual inspection	In-House/ EN 1616:1997 – 4.2. ASTM F1886	All samples pass
Dimensional inspection	In-House/ EN 1616:1997 – 4.3	All samples pass
Flow rate	ASTM F623-99	All samples pass
Tensile testing – catheter to connector	In-House	All samples pass
Tube hardness	In-House	All samples pass
Force to connect/ disconnect catheter connector to leg bag stepped connector	In-House	All samples pass
Strength of catheter	EN 1616:1997 – Annex A	All samples pass
Leak testing - catheter tube to connector	EN 1618:1997 – Annex C	All samples pass
Accelerated age testing – then all above	ASTM F1980, ASTM F88, ASTM F1929	All samples pass
EO & ECH residuals	ISO 10993-7:2008	All samples pass
Cytotoxicity, Irritation, sensitization	BS EN ISO 10993-10:2010	All samples pass
	BS EN ISO 10993-5:2009	All samples pass
Colour comparison	BS EN ISO 8836:2009	All samples pass

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All Samples passed the performance testing when tested against methods and criteria from both In-House test methods and relevant BS EN standards. The results of this testing which are included in TR079/12 show that the Classic™ Intermittent Catheters pass all performance tests and perform at least as well as both marketed predicate devices. TR079/12 can be found in section 12 of this document.

Although very similar in design and function, there are some differences between the Flexicare Intermittent catheter and its predicate devices listed within this submission.

The Flexicare Classic™ Intermittent Catheter is un-coated whilst the predicate BARD "Interglide" Intermittent Catheter has a Hydrophilic coating which aids insertion when submerged in water. However, users of un-coated intermittent catheters can use a lubricant (not supplied) if required which will aid insertion without needing a sterile water source.

The Flexicare Classic™ Intermittent Catheter also differs from the BARD "Interglide" and the Coloplast "Self-Cath" predicates as is includes a sliding tube grip, which is not present on the predicate devices. This prevents the user having to touch the invasive tube of the catheter during insertion, reducing the risk of urinary tract infection.

The Flexicare Classic™ Intermittent Catheter also differs from the predicate devices in available lengths, being available in a French size 20.

The Flexicare Classic™ Intermittent Catheter & Coloplast "Self-Cath" drainage funnels are Manufactured from PVC. This differs from the drainage funnel of the BARD "Interglide" sample which Is manufactured from TPE. This difference is not critical as both materials are flexible, able to be Colored and have an elastic nature, allowing a push fit connection to a drainage bag connector.

Signature of contact Person:

Chris Watkins

20-09-2013

----------End of 510k Summary----------

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 11, 2013

FLEXICARE MEDICAL LTD.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K132619
Trade/Device Name: Classic™ Intermittent Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: September 27, 2013
Received: September 30, 2013

Dear Mark Job,

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 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. 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,

Benjamin R. Fisher -S

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

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Indications for Use

510(k) Number (if known): K132619

Device Name: Classic™ Intermittent Catheter.

Indications for Use:

Classic™ intermittent catheters are intended for use in Male, Female and Paediatric patients when regular assisted bladder drainage has been instructed by a physician.
Classic™ intermittent catheters are indicated for use by individuals whose ability to void the bladder fully by natural bodily functions is impaired.

Prescription Use ✔ (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)

Benjamin R. Fisher -S
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