JAN 17 2014

510(k) Summary
Page 1 of 9

Date Prepared: 19-Dec-2013

Mediplus Ltd.
Unit 7, The Gateway Centre
Coronation Road, Cressex Business Park
High Wycombe, Bucks, HP12 3SU UK

Tel – +44 (0) 1494 551299
Fax – +44 (0) 1494 536333

Official Contact: Tim Ward
Operations Manager

Proprietary or Trade Name: Suprapubic Catheter and Introducer set

Common/Usual Name: catheter, suprapubic (and accessories)

Classification Name: catheter, suprapubic (and accessories)
KOB – CFR 876.5090
Class II

Predicate Devices: Fortune Medical – Suprapubic catheter – K014002
Fortune Medical – Foley Catheters - K980919
Rusch Suprapubic Catheter Kits – K970021
Cook Medical Urological Guidewires – K082536

Device Description:
Suprapubic catheters are Foley catheters that are placed with an introducer through a needle puncture or stab wound over the bladder to allow bladder irrigation and / or drainage of the bladder. They are available in two (2) tip styles, closed and open tip.

The introducer kit includes a number of components including: Scalpel, Syringe, 18 gauge needle, Dilator and Peelable sheath, and Guidewire

Indications for Use:
The Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder. For use no greater than 29 days.

Environment of Use:
Hospitals, sub-acute settings

510(k) Summary
Page 2 of 9
19-Dec-2013

Table 1 - Comparison to Predicates - Suprapubic Catheter – Open Tip style and Kits

Attribute	Proposed Mediplus Suprapubic	Predicate Fortune Suprapubic Catheter K014002	Predicate Rusch Suprapubic Kits K970021
Indications for Use	The Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder.	Intended for drainage of the bladder through a needle or stab wound over the bladder	Suprapubic kit/tray is used for suprapubic bladder catheterization and drainage of fluids to and from the urinary tract
Environments of use	Hospitals and sub-acute setting	Hospitals and sub-acute setting	Hospitals and sub-acute setting
Patient Population	Patients requiring bladder irrigation and / or drainage	Patients requiring bladder irrigation and / or drainage	Patients requiring bladder irrigation and / or drainage
Indwelling Time	No greater than 29 days	No greater than 29 days, though not specified	No greater than 29 days, though not specified
Single patient use, disposable	Yes	Yes	Yes
Basic Foley Catheter design	Foley Catheter with inflatable balloon and multiple drainage eyelets Open Tip style	Foley Catheter with inflatable balloon and multiple drainage eyelets Open Tip style	Foley Catheter with inflatable balloon and multiple drainage eyelets Tip style – 2 kinds mentioned
Size range of Foley	12 to 16 Fr	12 to 24 Fr	8 to 16 Fr
Components of a kit or Tray	Syringe Scalpel Needle Tocar / peelaway sheath Guidewire	This was a catheter only	Syringe Scalpel Needle Tocar / peelaway sheath Catheter plug

510(k) Summary
Page 3 of 9
19-Dec-2013

Substantial Equivalence Discussion

Indications for Use –
The indications for use for the Suprapubic Catheter and Introducer Set that is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder are identical for the proposed device when compared to the predicate – Fortune Medical Suprapubic catheter (K014002).

The indications for use for the Suprapubic Catheter and Introducer Set that is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder and includes various components to assist with the catheter placement are identical for the proposed device when compared to the predicate – Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The proposed device and the identified predicates have the identical indications for use and thus can be found substantially equivalent.

Technology and construction –
The design, manufacturing, shape, sizes, and materials are identical to the predicate – Fortune Medical Suprapubic catheter (K014002).
Discussion – The catheter utilized in the Mediplus device are purchased from Fortune Medical on an OEM basis in their finished final form except sterilization.

Environment of Use –
The environments of use of Hospitals and sub-acute setting are identical to predicates - Fortune Medical Suprapubic catheter (K014002) and Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The environments of use are identical to the predicate – Fortune Medical Suprapubic catheter (K014002) and Rusch Suprapubic catheter tray / kit (K970021).

Patient Population –
The patient population of Patients requiring bladder irrigation and / or drainage is identical to the predicates – Fortune Medical Suprapubic catheter (K014002) and Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The patient populations are identical to the predicates - Fortune Medical Suprapubic catheter (K014002) and Rusch Suprapubic catheter tray / kit (K970021).

Indwelling Time –
The indwelling time of no greater than 29 days is identical to the predicate – Fortune Medical Suprapubic catheter (K014002).
Discussion – The indwelling time is identical to the predicate – Fortune Medical Suprapubic catheter (K014002).

Convenience Kit –
Offering suprapubic catheters with components which assist in the placement of the catheter is equivalent to the predicate - Rusch Suprapubic catheter tray / kit (K970021).

510(k) Summary
Page 4 of 9
19-Dec-2013

The components offered are either identical or equivalent and include: syringes, trocar / sheaths, needles, scalpels. The differences of including a guidewire for placement are not substantially different.
Discussion – Offering a convenience kit is equivalent to the predicate - Rusch Suprapubic catheter tray / kit (K970021).

Non-Clinical Testing Summary –
We have performed testing of the balloon per ASTM F623 for Foley catheters for balloon burst, Volume maintenance and Deflation as well as testing per ISO 11070 for guidewires and Introducers for fracture, flexion, tensile strength, and corrosion.
Discussion – The catheter balloon and guidewire met the performance requirements of the standards.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicates have been found to be substantially equivalent.

Comparison to Predicates - Suprapubic Catheter – Closed Tip style and Kits

Table 5.2 below compares the key features of the proposed Mediplus Suprapubic catheter and Introducer Set with the identified predicates.

Indications for Use –
The indications for use for the Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder which is similar when compared to the predicate – Fortune Medical Foley catheter (K980919).

The indications for use for the Suprapubic Catheter with Introducer Set that is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder and includes various components to assist with the catheter placement are identical for the proposed device when compared to the predicate – Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The indications for use for the Suprapubic vs. a Foley Catheter are that the placement is different, i.e. needle puncture or stab wound over the bladder vs. inserted in the urethra, but the catheters are identical in design and function which is for drainage of the bladder. The proposed device and the identified predicate have similar indications for use and thus can be found substantially equivalent.

Technology and construction –
The design, manufacturing, shape, sizes, and materials are identical to the predicate – Fortune Medical Foley catheter (K980919).
Discussion – The catheter utilized in the Mediplus device are purchased from Fortune Medical on an OEM basis in their finished final form except sterilization.

510(k) Summary
Page 5 of 9
19-Dec-2013

Environment of Use –
The environments of use of Hospitals and sub-acute setting are identical to predicates - Fortune Medical Foley catheter (K980919) and Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The environments of use are identical to the predicate – Fortune Medical Foley catheter (K980919) and Rusch Suprapubic catheter tray / kit (K970021).

Patient Population –
The patient population of Patients requiring bladder irrigation and / or drainage is identical to the predicates – Fortune Medical Foley catheter (K980919) and Rusch Suprapubic catheter tray / kit (K970021).
Discussion – The patient populations are identical to the predicates – Fortune Medical Foley catheter (K980919) and Rusch Suprapubic catheter tray / kit (K970021).

Indwelling Time –
The indwelling time of no greater than 29 days is identical to the predicate – Fortune Medical Foley catheter (K980919).
Discussion – The indwelling time is identical to the predicate – Fortune Medical Foley catheter (K980919).

Convenience Kit –
Offering suprapubic catheters with components which assist in the placement of the catheter is equivalent to the predicate - Rusch Suprapubic catheter tray / kit (K970021).

The components offered are either identical or equivalent and include: syringes, trocar / sheaths, needles, scalpels.
Discussion – Offering a convenience kit is equivalent to the predicate - Rusch Suprapubic catheter tray / kit (K970021).

Non-Clinical Testing Summary –
We have performed testing of the balloon per ASTM F623 for Foley catheters for balloon burst, Volume maintenance and Deflation as well as testing per ISO 11070 for guidewires and Introducers for fracture, flexion, tensile strength, and corrosion.
Discussion – The catheter balloon and guidewire met the performance requirements of the standards.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicates have been found to be substantially equivalent.

510(k) Summary
Page 6 of 9
19-Dec-2013

Table 2 - Comparison to Predicates - Suprapubic Catheter – Closed Tip style and Kits

Attribute	Proposed Mediplus Suprapubic	Predicate Fortune Foley Catheter K980919	Predicate Rusch Suprapubic Kits K970021
Indications for Use	The Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder.	Intended for as urinary catheters to pass fluids to and from the urinary bladder	Suprapubic kit/tray is used for suprapubic bladder catheterization and drainage of fluids to and from the urinary tract
Environments of use	Hospitals and sub-acute setting	Hospitals and sub-acute setting	Hospitals and sub-acute setting
Patient Population	Patients requiring bladder irrigation and / or drainage	Patients requiring bladder irrigation and / or drainage	Patients requiring bladder irrigation and / or drainage
Indwelling Time	No greater than 29 days	No greater than 29 days, though not specified	No greater than 29 days, though not specified
Single patient use, disposable	Yes	Yes	Yes
Basic Foley Catheter design	Foley Catheter with inflatable balloon and multiple drainage eyelets Closed Tip style	Foley Catheter with inflatable balloon and multiple drainage eyelets Closed Tip style	Foley Catheter with inflatable balloon and multiple drainage eyelets Tip style – 2 kinds mentioned
Size range of Foley	12 to 16 Fr	12 to 24 Fr	8 to 16 Fr
Components of a kit or Tray	Syringe Scalpel Needle Tocar / peelaway sheath Guidewire	This was a catheter only	Syringe Scalpel Needle Tocar / peelaway sheath Catheter plug

510(k) Summary
Page 7 of 9
19-Dec-2013

Table 3 – Comparison to Predicate - Suprapubic Guidewire

Attribute	Proposed Mediplus Suprapubic Guidewire	Predicate Cook Urological Guidewires K082536
Indications for Use	The Suprapubic Guidewire is used to establish a tract and assist in the placement of a suprapubic catheter	Urological Guidewires are used for ureteral access, to establish a tract, and assist in the placement, replacement, and exchange of devices during urological procedures
Environments of use	Hospitals and sub-acute setting	Hospitals and sub-acute setting
Indwelling Time	None	None
Single patient use, disposable	Yes	Yes
Basic design	Wound wire that allows for flexibility Design has 3 sections of flexibility Rigid to assist in placement Semi-rigid Flexible tip, straight but deflects / curves with any resistance	Wound wire that allows for flexibility Design has 3 sections of flexibility Rigid to assist in placement J-shaped tip, deflects with any resistance
Dimensions	425mm long 0.93mm wide	Not available
Markings	Markings on the shaft to guide the user as to depth of insertion when used with Needle and Trocar	No markings
Performance testing	Tensile Strength Flexion Fracture Corrision	Tensile Strength Flexion and deflection

Substantial Equivalence Discussion

Table 5.3 above compares the key features of the proposed Mediplus Suprapubic guidewire with the identified predicate.

Indications for Use –

The indications for use for the Suprapubic Guidewire is indicated to establish a tract and assist in the placement of a suprapubic catheter which is similar when compared to the predicate – Cook Urological Guidewires (K082536).
Discussion – The proposed device and the identified predicate have the identical indications for use and thus can be found substantially equivalent.

510(k) Summary
Page 8 of 9
19-Dec-2013

Technology and construction –
The design, manufacturing, shape, size, and materials are substantially equivalent to the predicate – Cook Urological Guidewires (K082536).
Discussion – The Guidewire is substantially equivalent, the only difference is that the Mediplus Guidewire have a flexible tip vs. the predicate has a pre-formed "J" tip, however both are designed to deflect when the tip comes into contact with tissue.

Environment of Use –
The environments of use of Hospitals and sub-acute setting are identical to predicate - Cook Urological Guidewires (K082536).
Discussion – The environments of use are identical to the predicate – Cook Urological Guidewires (K082536).

Patient Population –
The patient population is identical to the predicate – Cook Urological Guidewires (K082536).
Discussion – The patient populations are identical to the predicate – Cook Urological Guidewires (K082536).

Convenience Kit –
Offering suprapubic guidewire as a component to assist in the placement of the catheter is equivalent to the predicate – Cook Urological Guidewires (K082536).
Discussion – Offering a convenience kit is equivalent to the predicate – Cook Urological Guidewires (K082536).

Non-Clinical Testing Summary –
We performed non-clinical testing comparing the Mediplus guidewire to the predicate Cook Urological Guidewires (K082536). Additionally we tested the guidewires per ISO 11070 for tensile strength, fracture flexion, and corrosion. The results demonstrated that they were equivalent.

Materials –
All of the components of the suprapubic catheters are identical to the predicates. Per ISO 10993-1 and G95-1 these would be considered as:

1) For the parts which are in the fluid pathway (indirect)
- External Communicating (indirect)
- Tissue contact
- Prolonged duration of use (> 24 hours but < 30 days)

and
(2) for the parts which contact the patient's mucosal membrane (direct)
- Surface Communicating (direct)
- Mucosal Membrane contact
- Prolonged duration of use (> 24 hours but < 30 days)

510(k) Summary
Page 9 of 9
19-Dec-2013

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicates have been found to substantially equivalent.

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

January 17, 2014

Mediplus Ltd.
Paul E. Dryden
Regulatory Consultant
Unit 7, The Gateway Centre
High Wycombe, Bucks
UK HP123SU

Re: K132890
Trade/Device Name: Suprapubic Catheter and Introducer Set
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: KOB
Dated: December 19, 2013
Received: December 20, 2013

Dear Paul E. Dryden,

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. 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 legally 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, and 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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number: K132890 (To be assigned)

Device Name: Suprapubic Catheter and Introducer Set

Indications for Use:

The Suprapubic Catheter and Introducer Set are indicated for drainage of the bladder through a needle puncture or stab wound over the bladder. For use no greater than 29 days.

Environment of use – hospital and sub-acute settings.

Patient population – Patients requiring bladder irrigation and / or drainage.

Prescription Use XX (Part 21 CFR 801 Subpart D) **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)

Herbert P. Lerner -S
2014.01.17 14:57:54 -05'00'