3. 510(K) SUMMARY

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: (612) 302-4987 Mobile: (612) 968-9567 Fax: (612) 287-4138 e-mail: usbes@coloplast.com
Name of Contact Person:	Brian E. Schmidt Regulatory Affairs Manager
Address/Contact:	1601 West River Road Minneapolis, MN 55411
Date Prepared:	July 24, 2014
Trade Name:	**Re-Trace Ureteral Access Sheath**
Common Name:	Ureteral Access Sheath
Classification Name:	Endoscope and Accessories 21 CFR 876.1500 Gastroenterology-Urology Devices Class II
Product Code:	FED

Legally Marketed Devices to Which Your Firm Is Claiming Equivalence:

The **Re-Trace Ureteral Access Sheath** is substantially equivalent in performance, indication, design and materials to **Re-Trace Ureteral Access Sheath**, cleared under Premarket notification # K102485.

Description of the Modified Device:

The **Re-Trace Ureteral Access Sheath** is comprised of the following components:

- Reinforced tube/sheath
- Introducer/dilator
- Connector
- Clip

The reinforced introducer sheath is composed of a polyether block amide (PEBA) outer surface with a hydrophilic coating. The inner surface of the sheath is polytetrafluoroethylene (PTFE). The sheath is reinforced with a stainless steel coil between the PEBA and PTFE materials. The distal tip of the sheath is fitted with a radiopaque ring. A white connector and orange clip is fitted on the proximal end of the sheath.

The introducer/dilator is a radiopaque polyvinyl chloride (PVC). The introducer is fitted with a luer connector on the proximal end and has a hydrophilic coating on the distal end. A guidewire entry and exit eye and three exit holes for fluid delivery are located at the distal end of the introducer.

Comparison to the Predicate Device

A 4cm length Nitinol tube is inserted in the injection channel of the introducer to stiffen the guide wire exit eye section of this introducer.

Intended Use Of The Device:

The **Re-Trace Ureteral Access Sheath** is used to establish a continuous conduit during urological endoscopic procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

The intended use of the modified device, as described in its labeling, has not changed as a results of the modification.

Technological Characteristics Compared To Predicate Device:

The **Re-Trace Ureteral Access Sheath** is substantially equivalent in performance, indication, design and materials to **Re-Trace Ureteral Access Sheath.**, cleared under Premarket notification # K102485. The only difference is that the **Re-Trace Ureteral Access Sheath** subject to this 510k contains a 4cm length Nitinol tube in the injection channel of the introducer to stiffen the guide wire exit eye section of the introducer compared to the predicate.

The modification has not altered the fundamental scientific technology of the predicate **Re-Trace Ureteral Access Sheath.**

Summary of Nonclinical Tests Submitted:

The following biocompatibility testing and bench testing comparing the modified device to the predicate device was conducted.

Biocompatibility

- Cytotoxicity-MEM Elution
- Irritation-Intracutaneous Reactivity
- Sensitization-Guinea Pig Maximization

Performance Testing

- Break force/Tensile
- Fluid Delivery
- Coefficient of Friction
- Kink force/Folding Resistance
- Tip Flexibility
- Sterile Barrier/Dye Penetration

Conclusions

The performance and biocompatibility testing provided in this submission demonstrates that the modified **Re-Trace Ureteral Access Sheath** is as safe and effective and performs as well as the predicate device and therefore supports the determination of substantial equivalence.

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

July 24, 2014

COLOPLAST A/S
Brian Schmidt
Regulatory Affairs Manager
1601 West River Road N
Minneapolis MN 55411

Re: K140523
Trade/Device Name: Re-trace Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Dated: June 25, 2014
Received: June 26, 2014

Dear Brian Schmidt,

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 Industry and Consumer Education 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 Industry and Consumer Education 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K140523

Device Name: **Re-Trace Ureteral Access Sheath**

Indications for Use:

The **Re-Trace Ureteral Access Sheath** is used to establish a continuous conduit during urological endoscopic procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

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)

Benjamin R. Fisher -S
2014.07.24 14:55:15 -04'00'