



November 2, 2020

Coloplast  
Michael Bumgarner  
Principal Regulatory Affairs Specialist  
1601 West River Road North  
Minneapolis, MN 55411

Re: K192904  
Trade/Device Name: SpeediCath Compact Set  
Regulation Number: 21 CFR§ 876.5130  
Regulation Name: Urological Catheter and Accessories  
Regulatory Class: II  
Product Code: GBM  
Dated: September 30, 2020  
Received: October 1, 2020

Dear Michael Bumgarner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews  
Director  
DHT3B: Division of Reproductive,  
Gynecology and Urology Devices  
OHT3: Office of GastroRenal, ObGyn,  
General Hospital and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K192904

Device Name

SpeediCath Compact Set

Indications for Use (Describe)

SpeediCath Compact Set is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. This device is intended for females only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SpeediCath Compact Set  
K192904 Traditional 510(k)



## 5.0 TRADITIONAL 510(K) SUMMARY

**Submitted by:** Coloplast A/S  
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Denmark

**Contact Person:** Michael Bumgarner  
Principal Regulatory Affairs Specialist  
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**Date of Summary:** 02 November 2020

**Trade or Proprietary Name:** SpeediCath Compact Set

**Common or Usual Name:** Catheter, Urethral

**Classification Name:** Urological Catheter and Accessories

**Regulation Number** 21 CFR 876.5130

**Classification:** Class II

**Product Code:** GBM (catheter, urethral)

**Review Panel:** Gastroenterology/Urology

**Predicate Device:** SpeediCath Compact Set, K121457  
The predicate device has not been subject to a design related recall.

SpeediCath Compact Set  
K192904 Traditional 510(k)



**Device Description:**

The SpeediCath Compact Set is a sterile, ready to use intermittent catheter for females. It is a single use catheter with an integrated urine bag.

The catheter is a hollow polyurethane tube that facilitates drainage of urine from the bladder through the urethra to the collection bag. It is available in three sizes FR/CH 10, FR/CH 12 and FR/CH 14.

The catheter is hydrophilic coated and placed in a sterile solution (swelling medium) inside a tube, which together with a cover and plug make up the primary packaging and the sterile barrier. The subject device is the same as the predicate device, apart from the swelling medium. The swelling medium resides between the catheter and the tube and lubricates the catheter. The swelling medium in the subject device contains polyethylene glycol (PEG), and the predicate contains polyvinylpyrrolidone (PVP).

**Indications for Use:**

SpeediCath Compact Set is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

This device is intended for females only.

The subject and predicate device have the same intended use.

**Performance Testing:**

Performance testing for SpeediCath Compact Set was conducted per applicable sections of voluntary and FDA consensus standards:

- Sterilization validation was performed by conducting dose setting per ISO 11137-1:2015 and ISO/TS13004: 2013
- Accelerated and Real Time aged shelf life testing according to ASTM F1980-16
- Biocompatibility testing (cytotoxicity, irritation, sensitivity, pyrogenicity and chemical characterization) according to ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1" (2016)
- Coefficient of friction according to ASTM D1894:2014
- Catheter coating friction per internal test method
- Finger test: adhesion, cohesiveness, uniformity, and smoothness per internal test method
- Corrosion according to EN ISO 20696:2018 and EN 1616:1997
- pH of the swelling medium per internal test method
- Osmolality of the swelling medium per internal test method

All tests met the pre-determined acceptance criteria.

SpeediCath Compact Set  
K192904 Traditional 510(k)



**Conclusion:**

The subject and predicate device have different technological characteristics, specifically a different swelling medium. This difference in technological characteristics does not raise different questions about safety and effectiveness.

The performance testing demonstrates the subject device is as safe and as effective as the predicate device.