April 15, 2024

Coloplast Corp
% Kristen Swanson
Regulatory Consultant
Kompass Regulatory Consulting
1583 Northrop St.
Falcon Heights, Minnesota 55108

Re: K233411
Trade/Device Name: Folysil® Silicone Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: October 6, 2023
Received: October 6, 2023

Dear Kristen Swanson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for Jessica K. Nguyen, Ph.D.
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K233411

Device Name
Folysil® Silicone Catheter

Indications for Use *(Describe)*
Folysil catheters are intended for use up to 30 days in adult and pediatric populations for:
- Bladder drainage by urethral catheterization,
- Bladder drainage by suprapubic catheterization for catheter replacement only (for non-grooved, straight 2-way Folysil catheters with a maximum balloon volume of 15mL).
- Bladder instillation of physiological saline solution.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# TRADITIONAL 510(k) SUMMARY

## I. SUBMITTER INFORMATION

| | |
|---|---|
| **Applicant** | Coloplast A/S |
| **Legal Manufacturer Address:** | Holtedam 1<br>3050 Humlebaek, Denmark |
| **Official Correspondent:** | Kristen Swanson<br>Regulatory Consultant<br>1583 Northrop St.<br>Falcon Heights, MN 55108<br>Phone: 651-245-2678<br>Email: uskrs@coloplast.com |
| **Date Prepared:** | April 12, 2024 |

## II. DEVICE NAME

| | |
|---|---|
| **Trade or Proprietary Name:** | Folysil® Silicone Catheter |
| **Common or Usual Name:** | Foley Catheter |
| **Classification Regulation:** | 21 CFR 876.5130 |
| **Device Class:** | II |
| **Product Code:** | EZL (Catheter, Retention Type, Balloon) |
| **Panel:** | Gastroenterology/Urology |

## III. PREDICATE DEVICES IDENTIFICATION

| | |
|---|---|
| **Primary Predicate device:** | Folysil® Silicone Catheter (K013174) |
| **Secondary Predicate device:** | Modified Pediatric Silicone Foley Catheter (K900031) |

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## IV. DEVICE DESCRIPTION

Folysil catheters are thin, hollow tubes equipped with a balloon, funnel and valve, to be inserted into the bladder by the urethral or supra-pubic approach to drain urine into a urine collection bag. Folysil catheters are held in place within the bladder by the balloon, which is filled with sterile water or with aqua-glycerin solution.

Folysil Silicone catheters are provided in a variety of configurations as shown in **Table 1.**

**Table 1: Folysil Silicone Catheter Range**

| | **Pediatric Use** | **Adult Use** |
|---|---|---|
| 2-way | 2-way | 2-way |
| Size, Fr | 6 Fr – 10 Fr | 12 Fr – 24 Fr |
| Tip Shapes | Straight round, Tiemann, Straight Open | Straight round, Tiemann, Straight Open |
| Balloon Volume, mL | 1.5mL – 3.0mL | 10 mL – 30 mL |
| Drainage eyes | 2 | 1-6 |
| Catheter Total Length, cm | 26 cm – 32 cm | 25 cm – 41 cm |
| Tube Surface | Smooth | Smooth and grooved |

## V. INDICATIONS FOR USE

Folysil catheters are intended for use up to 30 days in adult and pediatric populations for:
- Bladder drainage by urethral catheterization,
- Bladder drainage by suprapubic catheterization for catheter replacement only (for non-grooved, straight 2-way Folysil catheters with a maximum balloon volume of 15mL).
- Bladder instillation of physiological saline solution.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

**Table 2: Comparison between Subject Device and Predicate Device**

| **Comparison Element** | **Device Folysil® Silicone Catheters** | **Primary Predicate Device Porges Folysil Silicone Foley Catheters K013174** | **Secondary Predicate Device Modified Pediatric Silicone Foley Catheters K900031** |
|---|---|---|---|
| **Indications for Use** | Folysil catheters are intended for use up to 30 days in adult and pediatric populations for:<br>- Bladder drainage by urethral catheterization,<br>- Bladder drainage by suprapubic catheterization for catheter replacement only (for non-grooved, straight 2-way Folysil catheters with a maximum balloon volume of 15mL). | The 2-way PORGES Folysil silicone Foley catheter is used for urethral urinary catheterization for short-term drainage of vesical urines. Only straight 2-way PORGES Folysil silicone Foley catheter with a maximum 15 ml balloon volume may be used in a supra-pubic way (except the grooved catheters). | The PORGES paediatric silicone Foley catheter is used to pass fluids or from the urinary tract for children. |

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| Comparison Element | Device<br>Folysil® Silicone Catheters | Primary Predicate Device<br>Porges Folysil Silicone Foley Catheters<br>K013174 | Secondary Predicate Device<br>Modified Pediatric Silicone Foley Catheters<br>K900031 |
|---|---|---|---|
| | - Bladder instillation of physiological saline solution. | The 3-way PORGES Folysil silicone Foley catheter is used for urethral urinary catheterization to allow short term drainage of the vesical urines, irrigation/injection following surgery. | |
| **Target Population** | Pediatric and Adult, male and female | Pediatric and Adult, male and female | Pediatric patients. |
| **Duration of Use/Indwell time** | Up to 30 days. | Up to 30 days. | Up to 30 days. |
| **Common Name** | Catheter, Retention Type, Balloon | Catheter, Retention Type, Balloon | Catheter, Retention Type, Balloon |
| **French Size** | 6 – 24 Fr | 12 – 24 Fr | 6-10 Fr |
| **Length** | 25 – 41 cm | 25 – 41 cm | 30 – 35 cm |
| **Lumen** | 2-way | 2-way or 3-way | 2-way |
| **Balloon** | Yes | Yes | Yes |
| **Balloon Size** | 1.5mL-30mL | 10mL-30mL | 1.5 - 3mL |
| **Single Use** | Yes | Yes | Yes |
| **Sterile** | Yes, via EO | Yes, via EO | Yes, via EO |
| **Main Shaft Material** | Silicone | Silicone | Silicone |
| **Shelf Life** | 5 years | 5 years | 5 years |
| **Radiopaque line** | Yes | Yes, (only for neobladder catheters) | - |
| **Eyes** | Up to 6 | Up to 6 | up to 6 |
| **Tip Shapes** | Tiemann (coude tip), straight cylindrical," Over the guide" (straight open), straight round | Tiemann (coude tip), straight cylindrical, "Over the guide" (straight open), straight round | Tiemann (coude tip), straight cylindrical," Over the guide" (straight open), straight round |
| **Stylet/Introducer** | Yes (for pediatric sizes), Looped stylet | Not for adult sizes | Yes (for pediatric sizes), Straight stylet |

As evidenced by the above table, both the subject and the predicate devices have same intended use, but the subject and predicate devices have different technological characteristics. The differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

## VII. PERFORMANCE DATA

Device performance data was provided in support of the substantial equivalence determination.

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**Biocompatibility Testing**

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance document (2023), *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" | FDA"*. The subject device is an externally communicating device in contact with mucosal tissue for 30 days or more and following tests were conducted in accordance with the relevant ISO 10993 standards:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Material-mediated Pyrogenicity
- Genotoxicity – Ames and Mouse Lymphoma
- Implantation – 4 and 13 weeks
- Systemic toxicity – 13 weeks

The results of these tests demonstrate that the subject device is biocompatible.

**Bench Testing**

The following tests were performed per FDA recognized standard ASTM F623-19, ISO 20696:2018 and FDA guidance document (2020), *"Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway | FDA".*

- Visual tests
- Catheter integrity test
- Balloon size and shaft size
- Flow rate through drainage lumen
- Balloon integrity (resistance to rupture)
- Inflated balloon response to traction
- Balloon volume maintenance
- Deflation reliability test (failure to deflate)
- Funnel security of fit test
- Tensile test on funnel junction
- Tensile test on tip
- Simulation of use test
- Kink resistance test
- Radiopacity test
- Tensile test on valve junction

All pre-determined acceptance criteria were met for 14-24 Fr. catheters. The performance testing on the catheter sizes 6-12 Fr. was conducted according to the sponsor's internal test protocols as these catheter sizes are not covered under the above referenced standards. The protocol and acceptance criteria for these tests were scientifically adequate and clinically relevant, and the acceptance criteria were met for these tests as well.

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**Sterility, Packaging and Distribution**

The Folysil® Silicone Catheters were validated to be sterilized using ethylene oxide in accordance with ANSI/AAMI/ISO 11135:2014. To support the claimed shelf life, the Folysil Silicone Catheters were subjected to bench performance testing, transportation testing and package integrity testing to demonstrate that the product and package would be undamaged throughout the product life and maintain device sterility.

## VIII. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicates.