May 4, 2023

Dentsply Sirona
Laura Sobrin
Corporate Regulatory Affairs Manager
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K223756
Trade/Device Name: SimPro™ Now, GentleCath™ Hydrophilic
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter And Accessories
Regulatory Class: II
Product Code: EZD
Dated: December 15, 2022
Received: April 4, 2023

Dear Laura Sobrin:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen -S

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.

Submission Number *(if known)*

K223756

Device Name

SimPro™ Now
GentleCath™ Hydrophilic

Indications for Use *(Describe)*

SimPro™ Now is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.

GentleCath™ Hydrophilic is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.

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.

510(k) SUMMARY for
SimPro™ Now and GentleCath™ Hydrophilic
K223756

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17404

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Fax number: 717-849-4343

Date Prepared: April 3, 2023

2. Device Name:

- Proprietary Name: SimPro™ Now and GentleCath™ Hydrophilic
- Common Name: Intermittent urinary catheter
- Classification Name: Urological catheter and accessories
- CFR Number: 21 CFR 876.5130
- Device Class: Class II
- Product Code: EZD, Catheter Straight

3. Predicate and Reference Devices:

Type	Device Name	510(k)	Company Name
Predicate device	Hi-Slip® Plus	K062444	OASIS MEDIKAL A.S.
Reference device	GentleCath Glide Catheter	K161344	ConvaTec Limited

4. Description of Device:

The proposed devices: SimPro™ Now and GentleCath™ Hydrophilic are a range of sterile, single-use, urinary catheters designed as an intermittent pathway for drainage of the bladder. The catheters are available in a variety of lengths and French sizes to accommodate individual anatomy of both male and female users. Both Nelaton (straight tip) and Tiemann (Coudé tip) designs are available. Each catheter is individually packaged together with a sterile water sachet (packet) and an insertion guide. The water sachet is provided for wetting of the hydrophilic surface and is to be broken immediately before use in order to soak the tubing. The insertion guide is provided to minimize touching the catheter shaft directly during insertion and retraction.

5. Indications for Use:

SimPro™ Now is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.

GentleCath™ Hydrophilic is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.

6. Intended use population

SimPro™ Now and GentleCath™ Hydrophilic catheters are intended for male, female and pediatric patients (children, adolescents and transitional adolescents B (18 years old to less than 22 years old but treated like and adult)).

7. Comparison of Technological Characteristics:

The purpose of this Traditional 510(k) is to gain U.S. premarket clearance for the modification to the predicate device Hi-Slip® Plus (K062444).

- The proposed and predicate devices have the same intended use, patient population and indications for use.
- The proposed and predicate devices are sterile, single use, hydrophilic coated catheters, use the same operational principle, incorporate the same basic design, and have similar materials.
- The proposed and predicate devices have similar packaging configuration and are sterilized using the same method and processes.

The key differences between the predicate device (K062444) and the proposed devices are:

- Additional sizes and diameters
- Addition of insertion guide for non-touch technique
- Change in plasticizer material used in catheter body and funnel
- Updates made to Instructions for Use for reduction of soaking time and other minor updates
- Change in packaging materials supplier but similar materials and same configuration

An overview of the similarities and differences between the proposed devices and predicate device is given in Table FS-1.

8. Non-Clinical Performance Data

Non-clinical testing data that was submitted, referenced, or relied upon to demonstrate substantial equivalence includes:

a) Qualification of biological safety assessment according to ISO 10993-1:2018(E), *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process* and FDA Guidance "Use of International Standard ISO 10993-1". Testing performed included Chemical characterization, Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Subacute Systemic Toxicity, Genotoxicity, and Pyrogenicity.

b) Test methods for confirmation of sterile barrier systems and packaging validation testing following requirements in:
- ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISO 11607-2:2019, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
- ASTM F1929-15, *Standard test method for detecting seal leaks in porous medical packaging by dye penetration.*
- ASTM D4169-22, *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM D4332-14, *Standard Practice for Conditioning Containers Packages or Packaging Components for Testing*
- ASTM F88/F88M-15, *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- EN 868-5:2018, *Packaging for terminally sterilized medical devices – Part 5- Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods.*

c) Sterilization validation was performed according to
- ISO 11137-1:2006/(R)2015, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*
- ISO 11135:2014, *Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]*
- ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.*

d) Shelf life and Performance bench testing was performed per applicable sections of ISO 20696:2018, *Sterile urethral catheters for single use*, and internal test methods to document the following properties of the catheters:
- *Flow rate* was verified by the test method in Annex E of ISO 20696:2018.
- *Peak tensile force* was verified by the test method in Annex H of ISO 20696:2018.
- *Connector security* was verified by internal test method.
- *Kink stability* was verified by internal test method.
- *Friction* was verified by internal test method.
- *Water retention* was verified by internal test method.
- *Coefficient of friction* was verified by internal test method.
- *Packaging sterile integrity* was verified by internal test method.
- *Primary package seal strength* was verified by internal test method.
- *Catheter soaking time* prior to use according to the Instructions for Use was verified by internal test method.

All tests met the pre-determined acceptance criteria.

The results of the testing show substantial equivalence in performance of the proposed device when compared to the predicate device (K062444) and reference device (K161344).

9. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed SimPro™ Now and GentleCath™ Hydrophilic.

10. Conclusion

The proposed devices and the predicate device (K062444) have the same intended use and indications for use, are sterile, single use catheters, incorporate the same basic design, incorporate the same or very similar materials, and have similar packaging configuration. Performance data are included to address the safety and effectiveness of the proposed devices. The results of non-clinical bench testing, combined with the design, biocompatibility, and intended use comparison to the predicate device (K062444) demonstrate that the proposed devices are as safe, as effective and perform as well as the legally marketed device.

Table FS-1: Comparison of technological characteristics between proposed, predicate, and reference devices

Element	Proposed Devices		Predicate Device	Reference Device	Discussion
	SimPro™ Now	GentleCath™ Hydrophilic	Hi-Slip® Plus (K062444)	GentleCath Glide Intermittent Catheter (K161344)	
Product Code	EZD		EZD	GBM	Same as predicate device
Device for Prescription use	Yes		Yes	Yes	Same
Indications for Use	SimPro™ Now is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder. GentleCath™ Hydrophilic is for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.		Hi-Slip® Plus is launched for Clean Intermittent Catheterization-CIC treatment and is indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.	Intermittent catheters are indicated for routine transient intermittent drainage of the bladder. The catheter is inserted through the urethra. GentleCath Glide intermittent catheter is intended for adult use only.	Same as predicate device
Anatomical site	Bladder through the Urethra		Bladder through the Urethra	Bladder through the Urethra	Same
Patient population	Intended for male, female and pediatric patients (children, adolescents and transitional adolescents B (18 years old to less than 22 years old but treated like and adult)).		Intended for male, female and pediatric patients (children, adolescents and transitional adolescents B (18 years old to less than 22 years old but treated like and adult)).	Intended for male and female patients	Same as predicate device
Principal of operation	• Squeeze water pocket • Peel pack open • Insert catheter • Empty bladder • Withdraw catheter		• Squeeze water pocket • Peel pack open • Insert catheter • Empty bladder • Withdraw catheter	• Squeeze water pocket • Peel pack open • Insert catheter • Empty bladder • Withdraw catheter	Same

Element	Proposed Devices		Predicate Device	Reference Device	Discussion
	SimPro™ Now	GentleCath™ Hydrophilic	Hi-Slip® Plus (K062444)	GentleCath Glide Intermittent Catheter (K161344)	
	• Dispose device		• Dispose device	• Dispose device	
Catheter tip Configuration	Nelaton (Straight) tip & Tiemann (Coudé tip) tip		Nelaton (Straight) tip & Tiemann (Coudé tip) tip	Nelaton (Straight) tip & Tiemann (Coudé tip) tip	Same
Type/Sizes	Nelaton CH.8, 10, 12, 14, 16 & 18 in 15cm length Nelaton CH.6, 8, 10, 12, 14, 16 & 18 in 20cm length Nelaton CH.6, 8 & 10 in 30cm length Nelaton CH.8, 10, 12, 14, 16, 18, 20 & 22 in 40cm length Tiemann CH.10, 12, 14, 16, 18 & 20 in 40cm length	---------- Nelaton CH.8, 10, 12, 14 & 16 in 20cm length ---------- Nelaton CH.8, 10, 12, 14, 16 & 18 in 40cm length Tiemann CH.10, 12, 14, 16 &18 in 40cm length	---------- Nelaton CH.6, 8, 10, 12, 14, 16 & 18 in 20cm length Nelaton CH.6, 8 & 10 in 30cm length Nelaton CH.8, 10, 12, 14, 16, 18, 20, 22 & 24 in 40cm length Tiemann CH.10, 12, 14, 16 &18 in 40cm length	Nelaton CH.8, 10, 12, 14, 16 in 15cm length Nelaton CH.8, 10, 12, 14, 16 & 18 in 20cm length ---------- ---------- Tiemann CH.8, 10, 12, 14, 16 &18 in 40cm length	Similar To facilitate handling by female users, a shorter catheter (15cm) has been added to the proposed SimPro™ Now. With the exception of the 40cm Tiemann tip catheter which has been expanded to include an additional diameter of CH20, all other sizes are within the range of predicate device Hi-Slip Plus (K062444).
Catheter tube Material	Polyvinylchloride (PVC) + Dioctyl terephthalate (DEHT)		Polyvinylchloride (PVC) + Di(2-ethylhexyl) (DEHP)	Polyolefin Based Synthetic Thermoplastic Elastomer (POBE)	Same base material, different plasticizer as predicate device The proposed device is composed of identical base material (PVC) with a non-

Element	Proposed Devices		Predicate Device	Reference Device	Discussion
	SimPro™ Now	GentleCath™ Hydrophilic	Hi-Slip® Plus (K062444)	GentleCath Glide Intermittent Catheter (K161344)	
					phthalate plasticizer (DEHT). Biocompatibility testing was performed to address material formulation differences between the proposed and predicate device in support of substantial equivalence.
Hydrophilic surface coating	Polyvinylpyrrolidone (PVP) & NaCl		Polyvinylpyrrolidone (PVP) & NaCl	Hydrophilic additive within the base material (unknown)	Same as predicate device
Hydrophilic coating activation	Integrated water sachet with sterile water		Integrated water sachet with sterile water	Integrated water sachet with sterile water	Same
Catheter funnel	Color coded end-funnel with insertion guide		Color coded end-funnel No insertion guide	Color coded end-funnel with insertion sleeve	Similar to predicate and reference devices The proposed devices are provided with insertion guide to minimize touching the catheter shaft directly during insertion and retraction. This has the same functionality as the insertion sleeve in the reference device. Both predicate and proposed devices are composed of the same base material for the catheter funnel. The proposed funnel material contains a non-phthalate plasticizer.
Single Package	Paper and film peel pack		Paper and film peel pack	Paper and film peel pack	Similar Same packaging configuration and similar materials. Packaging testing has been conducted and included to address material formulation

Element	Proposed Devices		Predicate Device	Reference Device	Discussion
	SimPro™ Now	**GentleCath™ Hydrophilic**	**Hi-Slip® Plus (K062444)**	**GentleCath Glide Intermittent Catheter (K161344)**	
					and sterility integrity in support of substantial equivalence.
Sterilization method	Ethylene Oxide & gamma irradiation (water sachet)		Ethylene Oxide & gamma irradiation (water sachet)	Ethylene Oxide	Same as predicate device
Condition of Use	Single Use		Single Use	Single Use	Same
Shelf Life	3 years		3 years	18 months	Same as predicate device