DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 11, 2017

Dentsply Sirona
Karl Nittinger
Senior Manager, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, PA 17401

Re: K170487
Trade/Device Name: Navina Classic System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: August 4, 2017
Received: August 7, 2017

Dear Karl Nittinger:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170487

Device Name
Navina Classic System

Indications for Use *(Describe)*
The Navina Classic System is indicated for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management.

The Navina Classic System is intended to promote evacuation of the contents of the colon and rectum by instilling water into the lower part of the colon through a rectal catheter which incorporates an inflatable balloon.

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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510(k) SUMMARY
for
Navina Classic System

1.0 Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
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York, PA 17401

Contact Person: Karl Nittinger
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Date Prepared: 31 August 2017

2.0 Device Name:

- Proprietary Name: Navina Classic System
- Classification Name: Gastrointestinal Tubes and Accessories
- CFR Number: 876.5980
- Device Class: II
- Product Code: KNT

3.0 Predicate Device:

Predicate Device Name	510(k)	Company Name
Peristeen Anal Irrigation System	K140310	Coloplast A/S

4.0 Description of Device:

The Navina Classic System is indicated for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management.

The Navina Classic System is composed of a single use rectal catheter with an inflatable balloon, a water container, a control unit for manual control of instillation water flow and manual balloon inflation and deflation, and tubing with integral connectors for connection of the device components.

The Navina Classic System is intended to promote evacuation of the contents of the colon and rectum by instilling water into the lower part of the colon through the rectal catheter which incorporates an inflatable balloon.

5.0 Indications for Use:

The Navina Classic System is indicated for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management.

The Navina Classic System is intended to promote evacuation of the contents of the colon and rectum by instilling water into the lower part of the colon through a rectal catheter which incorporates an inflatable balloon.

6.0 Substantial Equivalence:

Technological Characteristics:

For the purpose of substantial equivalence, the proposed Navina Classic System is compared to the predicate Peristeen Anal Irrigation System cleared under premarket notification K140310.

Table 1a and b below summarizes the similarities and differences between the proposed Navina Classic System and the predicate Peristeen Anal Irrigation System (K140310).

Table 1a Similarities and Differences between the proposed and the predicate devices.

Element	**Proposed Device** ***Navina Classic System***	**Predicate Device** ***Peristeen Anal Irrigation System (K140430)***	**Difference between Proposed device and Predicate device**
Indications For Use	The Navina Classic System is indicated for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. The Navina Classic System is intended to promote evacuation of the contents of colon and rectum by instilling water into the lower part of the colon through a rectal catheter which incorporates an inflatable balloon.	The **Peristeen Anal Irrigation System** is intended to instill water into the colon through a rectal catheter - which incorporates an inflatable balloon - inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2-<12 years old), adolescent (12-<18 years old), transitional adolescent (18-<21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.	More narrow population for proposed device.
Prescription Device	Yes	Yes	None
Target Population	Patients who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management.	Patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.	Proposed device does not limit the target population to patients with neurogenic bowel dysfunction. Any patient suffering from fecal incontinence, chronic constipation, and/or time consuming bowel management is included in target population.
Age Groups	Adults	Children (2-<12 years old), adolescent (12-<18 years old), transitional adolescent (18-<21 years old) and adult	More narrow age group for proposed device.
Anatomical Site	Rectum (and lower colon)	Rectum (and lower colon)	None
Where Used	Health Care Facility and home use	Health Care Facility and home use	None
Retention in Bowel During Treatment	Rectal balloon catheter	Rectal balloon catheter	None
Bowel Irrigation Function	Irrigation fluid bag and pump (control unit) provided	Irrigation fluid bag and pump (control unit) provided	None
Single Use	Catheter is for single use Other parts are for repeated use	Catheter is for single use Other parts are for repeated use	None

Table 1a Similarities and Differences between the proposed and the predicate devices.

Element	Proposed Device *Navina Classic System*	Predicate Device *Peristeen Anal Irrigation System (K140430)*	Difference between Proposed device and Predicate device
Rectal Catheter Coating	Hydrophilic coating	Hydrophilic coating	None
Fluid for Activation of Catheter Coating	Water	Water	None
Fluid for Irrigation	Lukewarm water (97-100 °F)	Lukewarm water (97-100 °F)	None
Placement of Catheter	Rectum -balloon inflated above sphincter	Rectum -balloon inflated above sphincter	None
Balloon is Inflated With	Air	Air	None
Sterility	Provided non-sterile	Provided non-sterile	None
Biocompatibility per ISO10993	Meets standard	Meets standard	None

Table 1b
Similarities and differences regarding Contraindications and Precautions for Proposed and Predicate device (K140310)

Element	Proposed device *Navina Classic System*	Predicate device *Peristeen Anal Irrigation System (K140130)*	Difference between proposed and predicate device
Contra indications	You shall not use Navina Classic System if you have had one or more of the following:	Peristeen anal Irrigation must **not** be used in the following situations:	None
	• Anal or colorectal stenosis	Known anal or colorectal stenosis	None
	• Colorectal cancer	Colorectal cancer	None
	• Active inflammatory bowel disease	Active inflammatory bowel disease	None
	• Acute diverticulitis	Acute diverticulitis	None

Element	Proposed device *Navina Classic System*	Predicate device *Peristeen Anal Irrigation System (K140130)*	Difference between proposed and predicate device
	• You are within three months of anal or colorectal surgery	Within three months of abdominal, anal or colorectal surgery	Abdominal surgery included for Predicate device. According to consensus expert review (Emmanuel et al[1]) the absolute contraindication is "Within three months of rectal surgery". Contraindication for Proposed device is based on consensus expert review paper[1].
	• You are within 4 weeks of previous endoscopic polypectomy	Within 4 weeks of endoscopic polypectomy	None
	• Ischhaemic colitis	Ischhaemic colitis	None
	• During spinal cord shock phase	During spinal cord shock phase	None
	• Complex diverticular disease	Complex diverticular disease	None
	Navina Classic system shall not be used in patients who are pregnant.	In patients who are pregnant and have not used the system before. *If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.	None
	As the list of contraindications may not be exhaustive, healthcare professionals will always consider individual user factors as well	Since the list is not exhaustive, the physician/health care professional should always consider individual patient factors as well	None
Precautions	Always consult a health care professional specialized in TAI before using Navina Classic system	It is vital for your safety that you always consult a physician/health care professional specialized in Peristeen Anal irrigation before performing the irrigation procedure.	None
	This product is NOT recommended for children.	Peristeen anal Irrigation is not recommended for children below two years of age	More narrow user group for Proposed device

Element	Proposed device *Navina Classic System*	Predicate device *Peristeen Anal Irrigation System (K140130)*	Difference between proposed and predicate device
	Special caution must be shown if you have had any of the following:	Special caution must be shown if you have had any of the following:	None
	• Painful anorectal conditions -any condition which may cause pain or bleeding, e.g. anal fissure, anal fistula third or fourth grade of hemorrhoids	Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third or fourth degree haemorrhoids	None
	• Fecal impaction. If you are heavily constipated an initial clean out of your bowel must be performed before starting up the irrigation treatment	Fecal impaction/heavy constipation. If you are heavily constipated (fecally impacted) an initial clean-out of your bowels is mandatory before starting up the Peristeen Anal Irrigation procedure	None
	• Irradiation therapy in the abdominal or pelvic region	Irradiation therapy in the abdominal or pelvic region	None
	• Severe diverticulosis or diverticular abscess	Diverticular disease	Precautions for Proposed device are based on consensus expert review paper[1]. Consensus review state "Severe diverticulosis or diverticular abscess" as relative contraindication (Precaution)
	• Previous anal or colorectal surgery	Previous anal or colorectal surgery	None
	• Previous major pelvic surgery	Previous major pelvic surgery	None
	• Severe autonomic dysreflexia	Severe autonomic dysreflexia	None
	• Long term corticosteroid therapy	Long term corticosteroid therapy	None
	• Increased risk of hemorrhage or using anticoagulant therapy (not including aspirin or clopidogrel)	Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)	None
	• Changed stool pattern such as sudden diarrhea of unknown origin. The cause of diarrhea must be identified	Changed stool pattern such as sudden diarrhea of unknown origin. The cause of diarrhea must be identified	None

Element	Proposed device *Navina Classic System*	Predicate device *Peristeen Anal Irrigation System (K140130)*	Difference between proposed and predicate device
	• Rectal medication since the effect of such medication may be reduced by using anal irrigation	Rectal medication since the effect of such medication may be reduced by the anal irrigation	None
	Active inflammatory bowel disease (*contraindication*)	Inflammatory bowel disease (e.g. Crons disease or ulcerative colitis)	Active inflammatory bowel is a contraindication for Proposed device.
	Cancer in the abdominal and pelvic region	Cancer in the abdominal or pelvic region	None
	Severe cognitive impairment (unless caregiver is available to supervise/administer)	Severe cognitive impairment (unless caregiver is available to supervise/administer)	None

[1] Emmanuel *et al* (A V Emmanuel, K Krogh, G Bazzocchi, A.M Leroi, A Bremers, D Leder, D van Kuppevelt, G Mosiello, M Vogel, B Perrouin-Verbe, M Coggrave and P Christiensen (2013): "Consensus review of best practice of trans anal irrigation in adults". Spinal cord, 51, 732-738.)

Non-Clinical Performance Data:

The performance testing is divided into three parts; control unit, water container, rectal catheter, connectors, and system testing.

Performance testing of the control unit included:
- Control of air leakage
- Complete deflation of balloon (air release)
- Control of maximum pump force
- Ability to instantly stop water flow
- Control of water flow rate

Performance testing of the rectal catheter included:
- Hydrophilic coating at insertion and withdrawal
- Flexibility
- Even balloon inflation
- Balloon burst diameter
- Balloon burst volume
- Rectal catheter flow rate
- Rectal catheter flow rate after catheter kink

Performance testing of the water container included:
- Proper air pressure
- Accuracy of the scale of the water container

Performance testing of the connectors included:
- Control of air leakage
- Tensile and torque resistance after simulated repeated use.

Performance testing of the Navina Classic System included:
- System backflow verification testing

The performance of the Navina Classic System satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence

Biocompatibility has been assured by Cytotoxicity (ISO10993-5:2009), Irritation (ISO10993-10:2010), Sensitization (ISO10993-10:2010) and Genotoxicity (ISO10993-3:2014) analyses. The results of this testing demonstrates that the Navina Classic System is non-cytotoxic, non-irritating in support of substantial equivalence.

Additional analysis has been included to verify the potential for leachable compounds to be present after simulated repeated use. The results of this testing support substantial equivalence.

Clinical Performance Data:

No data from human clinical studies have been included to support the substantial equivalence of the Navina Classic System.

Conclusion Regarding Substantial Equivalence:

The Navina Classic System is a device for Anal Irrigation. By instilling water up into the lower part of the colon, through a rectal catheter, which incorporates an inflatable balloon, the peristaltic muscles in the bowel can be triggered and start to evacuate the colon and rectum.

The proposed Navina Classic System has the same intended use, incorporates the same fundamental technology, and has similar indications for use as does the predicate Peristeen Anal Irrigation System cleared under premarket K140310. The proposed device has a more narrowly defined indicated patient population when compared to the indicated use of the predicate device. Test data to verify the specified performance requirements of the subject device has been included. The results of this testing combined with the design, biocompatibility, and intended use comparison to the predicate device support the substantial equivalence of the Navina Classic System.