November 22, 2019

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

Re: K190977
Trade/Device Name: Navina Smart System and Navina Classic System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, FCE
Dated: October 22, 2019
Received: October 23, 2019

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. 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,

For:
Daniel Walter, Jr
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190977

Device Name
Navina Smart System and Navina Classic System

Indications for Use *(Describe)*

The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum.

The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.

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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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

510(k) UMMARY
For K190977
Navina Smart System and Navina Classic System

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: November 21, 2019

2. Device Name:
   - Proprietary Name: Navina Smart System and Navina Classic System
   - Classification Name: 876.5980 (*Gastrointestinal Tubes and Accessories*)
     876.5210 (*Enema Kit*)
   - Device Class: II
   - Primary Product Code: KNT [*Tubes, Gastrointestinal (And Accessories)*]
   - Secondary Product Code: FCE [*Enema Kit*]

3. Predicate Devices:

Predicate Device Name	510(k)	Company Name
Navina Classic System	K170487	Dentsply Sirona
Peristeen Anal Irrigation System	K140310	Coloplast A/S

4. Description of Device:

The purpose of this bundled 510(k) premarket notification is for the introduction of the Navina Smart System and the modification of the existing Navina Classic System, previously cleared in premarket notification K170487. The Navina Smart System and Navina Classic System are trans-anal irrigation (TAI) systems intended to assist in the management of bowel dysfunction.

The subject Navina Smart System is an electronically controlled, trans-anal irrigation system. The subject Navina Smart System consists of an electronic control unit, a water container and tubing set for water instillation, single-use, disposable rectal balloon catheters in two sizes (regular or small), and a disposable rectal cone catheter. The water container, tubing set and the regular (size) rectal balloon catheter utilized with the Navina Smart System are identical to the same components cleared under the original clearance of the predicate Navina Classic System in premarket notification, K170487.

With the Navina Smart control unit, the user controls water volume, irrigation speed, and rectal catheter balloon inflation. The Navina Smart system includes a mobile application in which users can save treatment data and rate their irrigation. The Navina Smart mobile application facilitates tracking of TAI treatment data (e.g., treatment duration, water volume used, rectal balloon size, etc.) but does not function in any way to control the function of the Navina Smart System itself.

The Navina Classic System is a manually operated trans-anal irrigation (TAI) system. The Navina Classic System, as subject of this "bundled" 510(k), consists of a manual control unit, a water container and tubing set for water instillation, single-use, disposable rectal balloon catheters in two sizes (regular or small), and a disposable rectal cone catheter. The water container, tubing set, and regular (size) rectal balloon catheter are identical to the same Navina Classic System components that were cleared under the system's original clearance in the predicate premarket notification, K170487.

5. Indications for Use:

Navina Smart System and Navina Classic System

The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum.

The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.

6. Substantial Equivalence:

Technological Characteristics

The subjects of this Traditional 510(k) are the introduction of the Navina Smart System and modification of the Navina Classic System, originally cleared in the predicate premarket notification K170487. This Traditional 510(k) is submitted as a "bundled" submission due to the following principles:

- The indications for use will be identical for the proposed Navina Smart System and the modified Navina Classic System.
- Components of the subject Navina Smart System: small rectal balloon catheter and cone catheter, are proposed for inclusion in the modified Navina Classic System as subject to this premarket notification and the supporting data associated with these new components are the same and relate to both systems.

For the purpose of substantial equivalence, the proposed Navina Smart System and modified Navina Classic System are compared to the predicate Navina Classic System, as originally cleared under premarket notification K170487, and to the predicate Peristeen Anal Irrigation System, cleared under premarket notification K140310.

Table 1a and 1b summarize the similarities and differences between the proposed Navina Smart System and the originally cleared predicate Navina Classic System (K170487) and the predicate Peristeen Anal Irrigation System (K140310).

Table 2a and 2b summarize the similarities and differences between the modified Navina Classic System and the originally cleared predicate Navina Classic System (K170487) and the predicate Peristeen Anal Irrigation System(K140310).

Table 1a: Similarities and Differences between the proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate Device Peristeen Anal Irrigation System (K140310)	Differences between proposed device and predicate devices
Indications For Use	The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum. The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.	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.	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	The proposed Navina Smart System has expanded indicated patient population compared to the primary predicate device Navina Classic System (K170487). The proposed Navina Smart System has the same indicated pediatric patient populations as the secondary predicate device: Peristeen Anal Irrigation System (K140310). However, the pediatric populations proposed in the indications for use for the subject Navina Smart System are constrained in comparison to those of the predicate Peristeen System (K140310) in order to clarify that use of the subject Navina Smart System device in these pediatric populations is proposed only in specific clinical circumstances and where less invasive therapies are not successful and to identify specific indicated uses of propose catheters.

Table 1a: Similarities and Differences between the proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate Device Peristeen Anal Irrigation System (K140310)	Differences between proposed device and predicate devices
Anatomical Site	Rectum (and lower colon)	Rectum (and lower colon)	Rectum (and lower colon)	None
Where Used	Health Care Facility and home use	Health Care Facility and home use	Health Care Facility and home use	None
Retention in Bowel During Treatment	Rectal balloon catheter and cone catheter	Rectal balloon catheter	Rectal balloon catheter	The proposed Navina Smart System also includes an additional cone catheter.
Bowel Irrigation Function	Irrigation fluid container and pump (control unit) provided	Irrigation fluid container and pump (control unit) provided	Irrigation fluid bag and pump (control unit) provided	None
Single Use	Catheters are for single use. Other parts are for repeated use	Catheter is for single use Other parts are for repeated use	Catheter is for single use Other parts are for repeated use	None
Rectal Catheter	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating	None
Fluid for Activation of Catheter Coating	Water	Water	Water	None
Fluid for Irrigation	Lukewarm water (97-100 F)	Lukewarm water (97-100 F)	Lukewarm water (97-100 F)	None
Placement of Catheter	Rectum -balloon inflated above sphincter. Cone catheter without balloon placed in rectum	Rectum -balloon inflated above sphincter	Rectum -balloon inflated above sphincter	The proposed Navina Smart System includes also an additional cone catheter.
Balloon is Inflated With	Air	Air	Air	None

Table 1a: Similarities and Differences between the proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate Device Peristeen Anal Irrigation System (K140310)	Differences between proposed device and predicate devices
Control Unit Design	Firmware controlled electronic control unit containing two pumps dependent on an energy source. One to inflate the balloon and one to instill water	Two manual pumps: One to inflate the balloon and one to instill water	One manual pump with a switch mode to inflate balloon and instill water	The Navina Smart Control Unit is an electro-mechanical design dependent on an energy source. Both predicates are dependent on manual power.
Control Unit Settings	The settings are personalized together with a health professional. The following can be set: 1. The size of the inflated balloon. 2. The amount of instilled water. 3. The flow rate.	The size of the balloon, the amount of water and the flow rate is dependent on manual pumping.	The size of the balloon, the amount of water and the flow rate is dependent on manual pumping.	Balloon size control, max fluid volume, and irrigation rate is software controlled according to preset parameters in the subject Navina Smart System.
Instillation of Water	Flow is generated by pressurizing the water container with air	Flow is generated by pressurizing the water container	Flow is generated by pressurizing the water container with air	None
Stop Water Flow	By releasing the button, the water flow is stopped.	Manual valve on the control unit.	Manual valve on the control unit.	Water flow is discontinued by closing a manual valve in the predicate devices. A water flow in the subject Navina Classic System is electro-mechanically controlled and is active only for the duration that the flow button is pressed.
Security Water Container	Safety valve to ensure proper air pressure and water flow	Safety valve to ensure proper air pressure and water flow	Safety valve to ensure proper air pressure and water flow	None
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	None

Table 1b: Similarities and differences regarding Contraindications and Precautions for proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between proposed and predicate device
Contraindications	Do NOT use Navina Systems if you have one or more of the following:	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
	Known anal or colorectal stenosis	Anal or colorectal stenosis	Known anal or colorectal stenosis	None
	Colorectal cancer	Colorectal cancer	Colorectal cancer	None
	Active inflammatory bowel disease	Active inflammatory bowel disease	Active inflammatory bowel disease	None
	Acute diverticulitis	Acute diverticulitis	Acute diverticulitis	None
	You are within three months of anal or colorectal surgery	You are within three months of anal or colorectal surgery	Within three months of abdominal, anal or colorectal surgery	None.
	You are within 4 weeks of previous endoscopic polypectomy	You are within 4 weeks of previous endoscopic polypectomy	Within 4 weeks of endoscopic polypectomy	None
	Ischemic colitis	Ischemic colitis	Ischemic colitis	None
	During Spinal cord Shock phase	During Spinal cord Shock phase	During Spinal cord Shock phase	None
	Complex diverticular disease	Complex diverticular disease	Complex diverticular disease	None
	Pregnant women	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

Table 1b: Similarities and differences regarding Contraindications and Precautions for proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between proposed and predicate device
Contraindications	As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well.	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	This product is NOT recommended for Children under 2 years.	This product is NOT recommended for children.	Peristeen anal Irrigation is not recommended for children below two years of age.	Same as secondary predicate Peristeen Anal Irrigation System (K140310).
	Children shall be accompanied by an adult caregiver until the caregiver considers the child able to perform the procedure by themselves.	Not applicable (Primary Predicate device was recommended for children)	Your first irrigation must be supervised by a health care professional.	Proposed device includes additional precaution information for improved understanding
	Always consult a health care professional specialized in TAI before using Navina systems.	Always consult a health care professional specialized in TAI before using Navina Classic system.	Always consult a health care professional specialized in Peristeen Anal irrigation before you perform the procedure.	None
	Only use Navina Systems for its intended use, as described in this instruction manual.	Only use Navina Systems for its intended use, as described in this instruction manual. (listed under important safeguards)	Please read all of the instruction warnings, contraindications and precautions before performing Peristeen Anal Irrigation procedure	None (information for primary predicate listed under important safeguards)
	Navina System is for a single user and should not be shared with other people.	Navina Classic is for a single user and should not be shared with other people. (listed under important safeguards)	Peristeen Anal Irrigation System must only be used by the same person. Do not share with others	None (information for primary predicate listed under important safeguards)
	The Navina catheters are available in two sizes	The Navina catheter is available in one size (noted in IFU)	The Peristeen catheters are available in two sizes (noted in IFU)	The proposed Navina Smart System also includes an additional cone catheter.

Table 1b: Similarities and differences regarding Contraindications and Precautions for proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between proposed and predicate device
Precautions	The Navina catheter regular is for adult only	The product is not recommended for Children	The regular catheter is intended for adults.	None
	Special care must be taken if you have or have had any of the following:	Special caution must be taken if you have or 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	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 hemorrhoids	None
	Fecal impaction. If you are heavily constipated an initial clean out of the bowel must be performed before starting up the irrigation treatment	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	Irradiation therapy in the abdominal or pelvic region	None
	Severe diverticulosis or diverticular abscess	Severe diverticulosis or diverticular abscess	Diverticular disease	Same as the primary predicate Navina Classic System (K170487).
	Previous anal or colorectal surgery	Previous anal or colorectal surgery	Previous anal or colorectal surgery	None
	Previous major pelvic surgery	Previous major pelvic surgery	Previous major pelvic surgery	None
	Severe autonomic dysreflexia	Severe autonomic dysreflexia	Severe autonomic dysreflexia	None
	Long term corticosteroid therapy	Long term corticosteroid therapy	Long term corticosteroid therapy	None
	Increased risk of hemorrhage or using anticoagulant therapy (not including aspirin or clopidogrel)	Increased risk of hemorrhage or using anticoagulant therapy (not including aspirin or clopidogrel)	Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)	None

Table 1b: Similarities and differences regarding Contraindications and Precautions for proposed Navina Smart System and the predicate devices: Navina Classic System and Peristeen Anal Irrigation System.

Element	Proposed Device Navina Smart System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between proposed and predicate device
Precautions	Changed stool pattern such as sudden diarrhea. The cause of diarrhea must be identified.	Changed stool pattern such as sudden diarrhea. 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
	Rectal medication since the effect of such medication may be changed by using anal irrigation	Rectal medication since the effect of such medication may be changed by using anal irrigation	Rectal medication since the effect of such medication may be reduced by the anal irrigation	None
	Active inflammatory bowel (contraindication)	Active inflammatory bowel (contraindication)	Inflammatory bowel disease (e.g. Crones disease or ulcerative colitis)	None
	Cancer in the abdominal or pelvic region	Cancer in the abdominal or 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)	Severe cognitive impairment (unless caregiver is available to supervise/administer)	None

Table 2a: Similarities and Differences between the modified Navina Classic System and the predicate devices-Navina Classic System and Peristeen Anal Irrigation System

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate Device Peristeen Anal Irrigation System (K140310)	Difference between the modified device and the predicate devices
Indications For Use	The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum. The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.	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.	The proposed Navina Smart System has expanded indicated patient population compared to the primary predicate device Navina Classic System (K170487). The proposed Navina Smart System has the same indicated pediatric patient populations as the secondary predicate device: Peristeen Anal Irrigation System (K140310). However, the pediatric populations proposed in the indications for use for the subject Navina Smart System are constrained in comparison to those of the predicate Peristeen System (K140310) in order to clarify that use of the subject Navina Smart System device in these pediatric populations is proposed only in specific clinical circumstances and where less invasive therapies are not successful and to identify specific indicated uses of propose catheters.

Table 2a: Similarities and Differences between the modified Navina Classic System and the predicate devices-Navina Classic System and Peristeen Anal Irrigation System

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate Device Peristeen Anal Irrigation System (K140310)	Difference between the modified device and the predicate devices
Anatomical Site	Rectum (and lower colon)	Rectum (and lower colon)	Rectum (and lower colon)	None
Where Used	Health Care Facility and home	Health Care Facility and home	Health Care Facility and home	None
Retention in Bowel During Treatment	Rectal balloon catheter and cone catheter without an inflatable balloon.	Rectal balloon catheter	Rectal balloon catheter	The modified Navina Classic System also includes an additional cone catheter which is also included for the proposed Navina Smart System.
Bowel Irrigation Function	Irrigation fluid bag and pump (control unit) provided	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.	Catheter is for single use. Other parts are for repeated use.	None
Rectal Catheter Coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating	None
Fluid for Activation of Catheter Coating	Water	Water	Water	None
Fluid for Irrigation	Lukewarm water (97-100 °F)	Lukewarm water (97-100 °F)	Lukewarm water (97-100 °F)	None
Placement of Catheter	Rectum -balloon inflated above sphincter. Cone without a balloon placed in the rectum.	Rectum -balloon inflated above sphincter.	Rectum -balloon inflated above sphincter.	The modified Navina Classic System includes also an additional cone catheter which is also included for the proposed Navina Smart System.
Balloon is Inflated With	Air	Air	Air	None
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	None

Table 2b. Similarities and differences regarding Contraindications and Precautions for modified Navina Classic System and predicate devices, Navina Classic System and Peristeen Anal Irrigation System.

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between the modified device and the predicate devices
Contraindications	Do NOT use Navina Systems if you have one or more of the following:	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
	Known anal or colorectal stenosis	Anal or colorectal stenosis	Known anal or colorectal stenosis	None
	Colorectal cancer	Colorectal cancer	Colorectal cancer	None
	Active inflammatory bowel disease	Active inflammatory bowel disease	Active inflammatory bowel disease	None
	Acute diverticulitis	Acute diverticulitis	Acute diverticulitis	None
	You are within three months of anal or colorectal surgery	You are within three months of anal or colorectal surgery	Within three months of abdominal, anal or colorectal surgery	None
	You are within 4 weeks of previous endoscopic polypectomy	You are within 4 weeks of previous endoscopic polypectomy	Within 4 weeks of endoscopic polypectomy	None
	Ischemic colitis	Ischemic colitis	Ischemic colitis	None
	During Spinal cord Shock phase	During Spinal cord Shock phase	During Spinal cord Shock phase	None
	Complex diverticular disease	Complex diverticular disease	Complex diverticular disease	None

Table 2b. Similarities and differences regarding Contraindications and Precautions for modified Navina Classic System and predicate devices, Navina Classic System and Peristeen Anal Irrigation System.

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between the modified device and the predicate devices
Contraindications	Pregnant women	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 may not be exhaustive, healthcare professionals will always consider individual user factors as well	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	This product is NOT recommended for Children under 2 years.	This product is NOT recommended for children.	Peristeen anal Irrigation is not recommended for children below two years of age.	Same as secondary predicate Peristeen Anal Irrigation System (K140310).
	Children shall be accompanied by an adult caregiver until the caregiver considers the child able to perform the procedure by themselves.	Not applicable (Primary predicate device was not recommended for children)	Your first irrigation must be supervised by a health care professional.	Proposed device includes additional precaution information for improved understanding
	Always consult a health care professional specialized in TAI before using Navina Systems	Always consult a health care professional specialized in TAI before using Navina Classic system	Always consult a health care professional specialized in Peristeen Anal irrigation before you perform the procedure.	None
	Only use Navina Systems for its intended use, as described in this instruction manual.	Only use Navina Systems for its intended use, as described in this instruction manual. (listed under important safeguards)	Please read all of the instruction warnings, contraindications and precautions before performing Peristeen Anal Irrigation procedure	None (information for primary predicate listed under important safeguards)
	Navina Systems is for a single user and should not be shared with other people.	Navina Classic is for a single user and should not be shared with other people. (listed under important safeguards)	Peristeen Anal Irrigation System must only be used by the same person. Do not share with others	None (information for primary predicate listed under important safeguards)

Table 2b. Similarities and differences regarding Contraindications and Precautions for modified Navina Classic System and predicate devices, Navina Classic System and Peristeen Anal Irrigation System.

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between the modified device and the predicate devices
Precautions	The Navina catheters are available in two sizes	The Navina catheter is available in one size (noted in IFU)	The Peristeen catheters are available in two sizes (noted in IFU)	Proposed device includes additional precaution information for improved understanding
	The Navina catheter regular is for adult only	The product is not recommended for Children	The regular catheter is intended for adults.	Proposed device includes additional precaution information for improved understanding
	Special care must be shown if you have or have had any of the following:	Special care must be taken if you have or 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	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 hemorrhoids	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. 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	Irradiation therapy in the abdominal or pelvic region	None
	Severe diverticulosis or diverticular abscess	Severe diverticulosis or diverticular abscess	Diverticular disease	Same as primary predicate Navina Classic System (K170487) which is also included for the proposed Navina Smart System.
	Previous anal or colorectal surgery	Previous anal or colorectal surgery	Previous anal or colorectal surgery	None

Table 2b. Similarities and differences regarding Contraindications and Precautions for modified Navina Classic System and predicate devices, Navina Classic System and Peristeen Anal Irrigation System.

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between the modified device and the predicate devices
Precautions	Previous major pelvic surgery	Previous major pelvic surgery	Previous major pelvic surgery	None
	Severe autonomic dysreflexia	Severe autonomic dysreflexia	Severe autonomic dysreflexia	None
	Long term corticosteroid therapy	Long term corticosteroid therapy	Long term corticosteroid therapy	None
	Increased risk of hemorrhage or using anticoagulant therapy (not including aspirin or clopidogrel)	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. The cause of diarrhea must be identified.	Changed stool pattern such as sudden diarrhea. 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
	Rectal medication since the effect of such medication may be changed by using anal irrigation	Rectal medication since the effect of the medication may be changed by using anal irrigation	Rectal medication since the effect of such medication may be reduced by the anal irrigation	None
	Active inflammatory bowel (contraindication)	Active inflammatory bowel (contraindication)	Inflammatory bowel disease (e.g. Crones disease or ulcerative colitis)	None
	Cancer in the abdominal or pelvic region	Cancer in the abdominal or pelvic region	Cancer in the abdominal or pelvic region	None

Table 2b. Similarities and differences regarding Contraindications and Precautions for modified Navina Classic System and predicate devices, Navina Classic System and Peristeen Anal Irrigation System.

Element	Modified Device Navina Classic System	Primary Predicate Device Navina Classic System (K170487)	Secondary Predicate device Peristeen Anal Irrigation system (K140310)	Difference between the modified device and the predicate devices
	Severe cognitive impairment (unless caregiver is available to supervise/administer)	Severe cognitive impairment (unless caregiver is available to supervise/administer)	Severe cognitive impairment (unless caregiver is available to supervise/administer)	None

7. Non-Clinical Performance Data:

The performance testing of the Navina Classic System and Navina Smart System which has been conducted to support substantial equivalence is divided into two parts; control unit and rectal catheters. The Navina Classic System and the Navina Smart System utilize the same range of accessories (i.e. water container, rectal catheters, and tubing). Only test data related to new components (rectal catheter Small, rectal catheter Cone, and Navina Smart control unit) which were not the subject of the original clearance of the Navina Classic System under K170487 have been included in this submission to support substantial equivalence.

Performance for the control units include:
- Control of air leakage
- Complete deflation of balloon (air release)
- Ability to instantly stop waterflow
- Control of water flow rate
- Control of water back flow
- Setting of balloon size (Navina Smart System)

Performance for the small rectal catheter:
- Balloon burst volume
- Flexibility
- Even balloon inflation
- Balloon burst diameter
- Rectal catheter flow rate
- Rectal catheter after catheter kink
- Hydrophilic coating

Performance for the conical rectal catheter:
- Hydrophilic coating at insertion and withdrawal
- Bonding strength between the catheter body and conical component.

Software verification and validation, as well as, electrical safety and electromagnetic compatibility testing for compliance with applicable standards and to validate the Navina Smart System against its design requirements has been included in support of substantial equivalence, including:

- Testing according to IEC 60601-1, *Medical electrical equipment - part 1: general requirements for basic safety and essential performance*.
- Testing according to IEC 60601-1-11, *Medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*
- Testing according to IEC 60601-1-2, *Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances --requirements and tests.*
- Testing according to IEC 60601-1-6, *Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.*
- Testing according to IEC 62304, *Medical Device Software – Software Life Cycle Processes.*
- Testing according to IEC 62133, *Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes- Safety Requirements for Portable Sealed Secondary Cells, and for Batteries made from them, for use in portable applications.*

- Testing according to IEC 62366-1, *Medical Devices - Part 1: Application of Usability Engineering to MedicalDevices.*

The results of the testing conducted in conformity with applicable standards support substantial equivalence.

8. Biocompatibility

Although there are no new patient contacting materials introduced as subject to this premarket notification, simulated use extraction according to ISO 10993-12, (Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials) chemical characterization, and toxicological analysis and assessment are included relating to the differences in indications for use between the subject and predicate devices.

The results of these analyses support substantial equivalence.

9. Clinical PerformanceData:

No data from human clinical studies have been included to support substantial equivalence.

10. Conclusion Regarding Substantial Equivalence:

The proposed Navina Smart System has the same intended use and has similar indications for use as the predicate Navina Classic System as cleared under K170487 and the predicate Peristeen Anal Irrigation System cleared under K140310. Certain technological characteristics relating to the control mechanism of the Navina Smart System are different when compared to the predicate Navina Classic System (K170487) and Peristeen (K140310). Performance data are included to address these differences. The results of this testing, combined with the design, biocompatibility, and intended use comparison to the predicate devices support the substantial equivalence of the Navina SmartSystem.

The modified Navina Classic System has the same intended use, incorporates the same fundamental technology, but has expanded indications for use as the predicate Navina Classic System as cleared under K170487. The expanded indications for use with respect to intended patient populations are similar to the predicate device cleared under K140310. Test data to verify the specified performance of the subject device has been included. The results of this testing combined with the design, biocompatibility, and intended use comparison to the predicate devices support the substantial equivalence of the modified Navina Classic System.