January 5, 2024

AnX Robotica Corporation
Tim Thomas
VP, Regulatory/Quality/Clinical
6010 W Spring Creek Parkway
Plano, Texas 75024

Re: K233229
Trade/Device Name: NaviCam Small Bowel Capsule Endoscopy System with NaviCam SB Capsule and NaviCam Tether
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: Class II
Product Code: NEZ, QUN
Dated: December 3, 2023
Received: December 6, 2023

Dear Tim Thomas:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
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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)*
K233229

Device Name
NaviCam Small Bowel Capsule Endoscopy System with NaviCam SB Capsule and NaviCam Tether

Indications for Use *(Describe)*

The NaviCam Small Bowel (SB) Capsule Endoscopy System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from 2 years of age.

The NaviCam Tether is an accessory of the NaviCam SB Capsule. It is intended to aid the capsule for visualizing the esophagus prior to the capsule's release into the gastrointestinal tract for a SB capsule endoscopy procedure in adults (≥ 22 years).

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

X. 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

NaviCam Small Bowel Capsule Endoscope System
with NaviCam SB Capsule and NaviCam Tether

510(k) Number K233229

1. SUBMITTER

Applicant's Name:
AnX Robotica Corporation
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Primary Contact:
Tim Thomas, RAC
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2. DATE PREPARED 9/28/2023

3. DEVICE

Trade Name: NaviCam Small Bowel Capsule Endoscopy System with NaviCam SB Capsule and NaviCam Tether

Classification Code:
Name: Ingestible telemetric gastrointestinal capsule imaging system
Product Codes: NEZ, QUN
Regulation No: 876.1300
Class: II
Classification Panel: Gastroenterology/Urology

4. PREDICATE DEVICES

Primary – Given PillCam Platform with PillCam SB Capsules, Given AGILE Patency System (K090557).

Reference – NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether, NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether (K221608).

5. DEVICE DESCRIPTION

The NaviCam Small Bowel Capsule Endoscopy System is an endoscopic capsule imaging system intended to obtain images of the small bowel. It is comprised of the following components:

a. **Capsule:** The disposable, ingestible NaviCam Small Bowel Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via an RF communication channel to the NaviCam Data Recorder located outside the body**.**
b. **Data recorder:** The Data Recorder is an external receiving/recording unit that receives and stores the acquired images from the capsule.
c. **ESView Software:** The ESView is a software application for processing, analyzing, storing, and viewing the acquired images collected from the NaviCam Data Recorder to create a video of the images. The software also includes a reporting function to create detailed clinical reports and a capsule endoscopy atlas.
d. **Locator:** The Locator is a handheld device that is used to turn the NaviCam Capsule on. It is also used for determining if the capsule is still in the body when the patient is not sure whether he/she expelled it.
e. **Tether:** The NaviCam Tether is a disposable product, which serves as an accessory to the NaviCam SB Capsule to allow for examination of the esophagus prior to releasing the NaviCam SB Capsule into the small bowel.

6. INDICATIONS FOR USE

The NaviCam Small Bowel (SB) Capsule Endoscopy System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from 2 years of age.

The NaviCam Tether is an accessory of the NaviCam SB Capsule. It is intended to aid the Capsule for visualizing the esophagus prior to the capsule's release into the gastrointestinal tract for a SB capsule endoscopy procedure in adults ($\geq$ 22 years).

7. SUBSTANTIAL EQUIVALENCE

Indications

The proposed indications for use of the NaviCam Small Bowel Capsule Endoscope System with NaviCam SB Capsule and NaviCam Tether are:

The NaviCam Small Bowel Capsule Endoscopy System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

The NaviCam Tether is an accessory of the NaviCam SB Capsule. It is intended to aid the Capsule for visualizing the esophagus prior to the capsule's release into the gastrointestinal tract for a SB capsule endoscopy procedure in adults (≥ 22 years).

The first part of the indications for use of the NaviCam Small Bowel Capsule Endoscope System with NaviCam SB Capsule and NaviCam Tether are the exactly the same to the indications for use of the FDA clearance for the Given PillCam Platform with PillCam SB Capsules, Given AGILE Patency System (K090557):

The Given PillCam® Platform with the PillCam SB Capsules is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

The second part of the indications for use of the NaviCam Small Bowel Capsule Endoscope System with NaviCam SB Capsule and NaviCam Tether are the same as the second part of the indications for use of the FDA clearance NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether, NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether (K221608) except for clarifying small bowel instead of stomach as the next capsule endoscope procedure along with removing "not magnetically maneuvered" since the NaviCam SB capsule is not magnetically maneuvered:

The NaviCam Stomach Capsule is intended for visualization of the stomach of adults (>/=22 years) with BMI < 38. The system can be used in clinics and hospitals, including ER settings.

The NaviCam Tether is an accessory of the NaviCam Stomach Capsule. It is intended to aid the Capsule for visualizing the esophagus (not magnetically maneuvered) prior to the Capsule's release into the stomach for a stomach capsule endoscopy (MCCE) procedure.

Technological Characteristics

The technological characteristics of the NaviCam Small Bowel Capsule Endoscope System are equivalent to the Given PillCam Platform with PillCam SB Capsules. Both systems utilize a capsule to acquire images of the small bowel, transmit the images to a data recorder, and then process the images via a software program to create a video for physician review. The capsules are very similar in size and material.

The technological characteristics of the non-sterile pre-assembled SB NaviCam Tether are very similar to Stomach NaviCam Tether with the main differences being non-sterile vs. sterile and being pre-assembled vs. separate devices (capsule and tether being packaged separately).

The Given PillCam SB Capsule has been non-sterile since its original clearance over 20 years ago therefore has a long history with no sterility issues. Therefore, the NaviCam Small Bowel Capsule as a non-sterile capsule will be identical to the predicate device from a technology perspective.

No changes to the equipment nor the software have been made, just the indication for use statement has been expanded, the change to non-sterile for the capsule, and the addition of the non-sterile pre-assembled NaviCam Tether accessory.

8. PERFORMANCE DATA

Clinical Experience

A summary of the clinical experience for children between the ages of 2 and 21 is shown in Table 1 below (publications included in Section 21).

Table 1 – Summary of Clinical Publications

No.	Publication	# of Patients	Avg Age	Min Age	Max Age
Current Publications (2011-2022)					
1	Oliva et al	22	12.5	4	17
2	Hijaz et al	27	13.5	4	18
3	Urs et al	58	12.7	1	18
4	Bass et al	3	8	7	16
5	Casciani et al	60	14	6	18
6	Cohen et al	277	15	3.4	23
7	Goldstein et al	14	4.5	1	16
8	Ohmiya et al	364	8	1	15
9	Cohen et al	18	13.3	10	16
Totals/Avg/Min/Max		**843**	**11.3**	**1**	**23**
Meta Analysis (2001-2010)					
10	Cohen et al	**723**	**11.0**	**0.8**	**18**
Totals/Avg/Min/Max		**1566**	**11.1**	**0.8**	**23**

A meta-analysis entitled *Use of Capsule Endoscopy in Diagnosis and Management of Pediatric Patients; Based on Meta-Analysis* was published in 2011 by Cohen et al. It was a summary of published pediatric trials conducted between January 2001 and May 2010. These published trials were used to support the Given PillCam Platform with PillCam SB Capsules, Given AGILE Patency System (K090557) clearance.

There have been nine additional studies conducted on children since the meta-analysis. The total number of patients totals 843 vs. 723 in the meta-analysis thus providing a equivalent comparison. The average and range of ages is also very similar; (1) the average

for the current data is 11.3 years old vs. 11.0 for the meta-analysis, and (2) the age range for the current data is 1-23 years old vs. 0.8-18 for the meta-analysis.

The company believes the clinical data confirms the original meta-analysis and confirms the use of small bowel capsule endoscopy in children to 2 years old. Since the PillCam SB Capsule and the NaviCam SB Capsule are essentially the same size, the clinical data proves that the NaviCam Small Bowel Capsule is safe for use in children. Therefore, the clinical data supports the indication for use expansion to 2 years old for the Capsule portion of the NaviCam SB Capsule Endoscope System with NaviCam SB Capsule and NaviCam Tether. The intended population for the tether is Adults $\geq$ 22 years of age.

Bench Testing

The NaviCam SB Capsule Endoscope System demonstrated compliance to the Special Controls in the previous submissions (K221590) and the hardware/software of the system has not changed but only the NaviCam Tether and the packaging. Bench testing confirms compliance with the Special Controls for the NaviCam Tether and the new packaging.

All the V&V tests of the NaviCam Small Bowel Capsule Endoscopy System with NaviCam SB Capsule and NaviCam Tether successfully met their acceptance criteria thus validating the performance of the system without raising any new safety or effectiveness concerns.

9. CONCLUSION

The expansion of the indications for use does not affect the performance of its parent device, the NaviCam Small Bowel Endoscope System, and does not pose any new risks to the patient as demonstrated using the device in clinical settings.

The change from sterile to non-sterile does not affect the performance of its parent device, the NaviCam Small Bowel Endoscope System, and does not pose any new risks to the patient as demonstrated by over 20 years of utilizing a non-sterile small bowel capsule in clinical use and clinical trials.

The change to pre-assembled capsule and tether does not affect the performance of its parent device, NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether, NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether and does not pose any new risks to the patient. This change reduces risk by having a pre-assembled capsule and tether vs. having health care providers attach the capsule to the tether which is inherently more variable than the manufacturing process.