April 13, 2023

AnX Robotica Corp.
Cathlena Martinez
Regulatory and Clinical Affairs Manager
6010 W Spring Creek Pkwy
Plano, TX 75024

Re: K230694
Trade/Device Name: NaviCam Xpress Stomach System, NaviCam Xpress System
Regulation Number: 21 CFR 876.1310
Regulation Name: Magnetically maneuvered capsule endoscopy system
Regulatory Class: Class II
Product Code: QKZ
Dated: March 13, 2023
Received: March 14, 2023

Dear Cathlena Martinez:

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,

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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K230694

Device Name
NaviCam Xpress Stomach System

Indications for Use *(Describe)*
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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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

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# 510(K) SUMMARY
# NaviCam Xpress Stomach System
# GastroScan feature Software Addition
**510(k) Number _____**

## 1. SUBMITTER

**Applicant's Name:**
AnX Robotica, Corp.
6010 W. Spring Creek Parkway
Plano, TX 75024
Phone: (469) 606-9495

**Primary Contact:**
Cathlena Martinez, CQA
Manager, Regulatory/Clinical
Phone: (859) 801-8517
Email: lena.martinez@anxrobotics.com

## 2. DATE PREPARED 03/09/2023

## 3. DEVICE

**Trade Name:** NaviCam Xpress Stomach system (NaviCam Xpress system)

**Classification Code:**
**Name:** Magnetically maneuvered capsule endoscopy system
**Product Code:** QKZ
**Regulation No:** 876.1310
**Class:** II
**Classification Panel:** Gastroenterology/Urology

## 4. PREDICATE DEVICES

**Primary predicate**– NaviCam Xpress Stomach system (NaviCam Xpress system) cleared under the 510(k) submission K203192.

**Reference**– NaviCam Capsule Endoscope System with NaviCam Stomach Capsule (hereafter "NaviCam Stomach System") granted the De-Novo submission under DEN190037.

## 5. DEVICE DESCRIPTION

The NaviCam Xpress Stomach System is a novel endoscopic capsule imaging system intended to obtain images of the stomach. It differs from passive capsule endoscopy systems in that it uses magnetic fields to allow the position of the capsule within the stomach to be controlled by an operator.
The NaviCam Xpress Stomach System includes the following key components:

1. Ingestible capsule (CP-US-7005) for obtaining images.
2. Data recorder (MC-US-1006) for logging image data.
3. Locator (SB-US-2006) for turning on the capsule and for determining if the capsule is still in the body.
4. Controller, NaviEC-2000 (MC-US-1002) with the NaviCtrl software that allows the navigation of the capsule within the stomach.
5. ESView software for review of the images obtained by the capsule and generating reports.
6. Optional Accessory: NaviCam Tether (ES-US-7005) for aiding the capsule in visualizing the esophagus.

## 6. INDICATIONS FOR USE

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.

## 7. SUBSTANTIAL EQUIVALENCE

***Intended Use/ Indications for Use***

There are no proposed changes to the indications for use of the NaviCam Xpress system.

***Technological Characteristics***

The NaviCam Xpress system (subject device) and predicate device (NaviCam Xpress system) system components are identical to the components of the currently marketed predicate device. Both the subject device and the predicate device, use the same mechanisms to fulfill their identical intended use, and share the same technological characteristics, respectively. The subject device operates using the same technology and technological characteristics as the currently marketed predicate device.

Both the subject device, and reference device, are technologically similar which are capsule endoscopy systems comprised of four elements: a capsule, a data recorder, software, controller and a workstation. In both devices the capsule is intended to be used as part of a system to visualize the gastrointestinal (GI) tract.

The only difference between the subject device and the currently marketed predicate device is a change to the NaviCtrl software and labeling for the subject device to add the GastroScan feature to align with the reference device (NaviCam Stomach system) software features which include the GastroScan (previously known as macro command) feature.

## 8. PERFORMANCE DATA

**Non-Clinical Performance Testing/ Bench Testing:**

Non-clinical performance and bench testing was completed to assess the performance of the NaviCam Xpress system with the updates to the NaviCtrl software to include the GastroScan feature. The data provided in this 510(k) submission shows that the device performs as intended based on the non-clinical bench testing. The list of these tests is provided in Table 8-1.

**Table 8-1: List of Non-Clinical Tests Completed on NaviCam Xpress Stomach System NaviCtrl Software with GastroScan feature.**

| Non-clinical/ Bench Testing |
|---|
| Software Verification Testing |
| Human Factors Engineering/ Usability Testing/ Evaluation |

**Animal and Clinical Performance Testing:**

No additional Animal and clinical performance testing were conducted.

**Clinical Experience**

No additional clinical literature has been provided in this submission. The previously submitted clinical evidence provided as part of the reference device De Novo, DEN190037, and primary predicate device 510k, K203192, submissions remain applicable and relevant to the subject device.

## 9. CONCLUSION

The NaviCam Xpress NaviCtrl software with GastroScan is a low-risk, device software component of the NaviCam Xpress Stomach system. The addition of the GastroScan feature to align with the previously approved marketed device, NaviCam Stomach system (DEN190037) and its component software, does not affect the indications and performance of the predicate device, and does not pose any new risks to the patient as demonstrated by the performance bench testing and software risk analysis, and cybersecurity FMEA risk analysis evaluations.