October 3, 2023

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

Re: K231960
Trade/Device Name: NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Capsule and NaviCam Tether
Regulation Number: 21 CFR 876.1310
Regulation Name: Magnetically Maneuvered Capsule Endoscopy System
Regulatory Class: Class II
Product Code: QKZ
Dated: June 30, 2023
Received: July 5, 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,

Sivakami Venkatachalam -S

for
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)*
K231960

Device Name
NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule and NaviCam Tether

Indications for Use *(Describe)*
The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients => 6 years old with BMI =< 65 and a waist circumference =< 77 inches. 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.

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510(K) SUMMARY

NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether

510(k) Number K231960

1. SUBMITTER

Applicant's Name:
AnX Robotica, Corp.
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Phone: (469) 606-9495

Primary Contact:
Tim Thomas, RAC
VP, Regulatory/Quality/Clinical
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Email: tim.thomas@anxrobotics.com

2. DATE PREPARED 06/30/2023

3. DEVICE

Trade Name: NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether

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 – NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether (K221608).
References – Given PillCam Platform with PillCam SB Capsules with PillCam SensorBelt (K103088) and Given PillCam Platform with PillCam SB Capsules, Given AGILE Patency System (K090557).

5. DEVICE DESCRIPTION

NaviCam® Xpress Stomach Capsule Endoscope System enables the operator to control the capsule endoscope inside the stomach. The capsule endoscope can be moved in any

direction during examination. The direction and angulation of the capsule camera head can be adjusted in real-time, hence realizing complete control of capsule endoscope movement and attitude during examination in the X left and right, Y forward and backward, Z up and down directions as well as rotation clockwise and counterclockwise.

6. INDICATIONS FOR USE

The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥ 6 years old with BMI ≤ 65 and a waist circumference ≤ 77 inches. 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

Indications

The proposed indications for use of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether, are:

The NaviCam Xpress Stomach Capsule is intended for visualization of the stomach of patients ≥ 6 years old with BMI ≤ 65 and a waist circumference ≤ 77 inches. 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.

The indications for use of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether are the same to the indications for use of the previous FDA clearance except for the expanded age limitation and BMI limitation based on clinical data and bench testing. The changes are similar to Given PillCam indications that expanded the age limit and expanded the BMI limit based on available clinical data.

Technological Characteristics

The technological characteristics of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether are equivalent (the same system) to the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule and NaviCam Tether. No changes to the equipment nor the software have been made, just the indication for use statement has been expanded.

8. PERFORMANCE DATA

Clinical Experience

The company is providing articles on the use of the NaviCam Stomach Capsule System that were published in the scientific literature along with unpublished clinical reports. The clinical data demonstrate using the system on lower age patients and higher BMI doesn't affect performance of the device. This real-world evidence demonstrates the safety and adds value by reaching additional patients that would benefit from the NaviCam Xpress Stomach Capsule System procedure. The NaviCam Xpress Stomach Capsule System procedure does not require sedation which is particularly important for children and obese patients from a procedure risk perspective.

Bench Testing

The company provided technical data demonstrating capsule and system performance would not be affected by increasing the BMI of the patient up to the limitations stated in the report.

9. CONCLUSION

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