November 22, 2022

AnX Robotica Corp
Tim Thomas
VP, Regulatory/Quality/Clinical
6010 W. Spring Creek Parkway
Plano, TX 75024

Re: K221608
Trade/Device Name: NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether, NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach 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: October 24, 2022
Received: October 26, 2022

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 (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,

Glenn B. Bell -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)*
K221608

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

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.

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510(K) SUMMARY

NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether
NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule and NaviCam Tether
510(k) Number K221608

1. SUBMITTER

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

Primary Contact:
Tim Thomas, RAC
VP, Regulatory/Quality/Clinical
Phone: (770) 480-2911
Email: tim.thomas@anxrobotics.com

2. DATE PREPARED 11/17/2022

3. DEVICE

Trade Name: NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether
NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress 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 Capsule Endoscope System with NaviCam Stomach Capsule ("NaviCam System") granted the De-Novo submission under DEN190037. NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) cleared under K203192.
Reference – Given Imaging PillCam® Express™ Video Capsule Delivery Device ("PillCam Delivery Device") cleared under K101200.

5. DEVICE DESCRIPTION

The NaviCam Capsule and NaviCam Tether are disposable sterile products, which serve as an accessory to the NaviCam Capsule Endoscope System and the NaviCam Xpress Stomach Capsule Endoscope System to allow for examination of the esophagus prior to releasing the NaviCam Capsule into the stomach. The NaviCam Tether is comprised of a tube which on one end is attached to a capsule cradle and on the other end is attached to a syringe connector. The capsule cradle holds the capsule in place while examining the esophagus. The tube is used to control the downward speed of the capsule in the esophagus. The syringe connector serves for releasing the capsule by attaching to it a standard syringe filled with air. After the examination of the esophagus is accomplished, the syringe piston is pushed to release the capsule for examining the stomach with the NaviCam Capsule Endoscope System or the NaviCam Xpress Stomach Capsule Endoscope System.

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

Indications

The proposed indications for use of the NaviCam Stomach Capsule and NaviCam Tether, as an optional accessory to the NaviCam Capsule Endoscope System and the NaviCam Xpress Stomach Capsule Endoscope System, are:

> *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.*

The indications for use of the NaviCam Stomach Capsule and NaviCam Tether complement the indications for use of the NaviCam Capsule Endoscope System and the NaviCam Xpress Stomach Capsule Endoscope System, as appropriate for an optional accessory intended to supplement/augment the performance of the parent device.

Technological Characteristics

The technological characteristics of the NaviCam Stomach Capsule and NaviCam Tether is substantially similar to the PillCam Delivery Device. Both devices are comprised of three elements: a capsule cradle/holder, a tube/catheter, and a syringe/syringe connector. In both

devices the capsule holder/cradle is designed to hold the capsule in place and in both devices an air-filled syringe is used to pneumatically release the capsule from the cradle/holder.

8. PERFORMANCE DATA

Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess the performance and biocompatibility of the NaviCam Stomach Capsule and NaviCam Tether. The data provided in this 510(k) submission shows that the device is biocompatible and performs as intended based on the bench testing. The list of these tests is provided in Table 8-1.

Table 8-1: List of Non-Clinical Tests Completed on NaviCam Tether

Biocompatibility
Cytotoxicity
Sensitization (0.9% NaCl)
Sensitization (Sesame Oil)
Intracutaneous Reactivity
Bench Testing
Third Party Performance Test
Product Verification Test v2
pH Tolerance Test
Bite Force Test
Battery Life Test

Animal and Clinical Performance Testing:

Animal and clinical performance testing was not conducted.

Clinical Experience

The company provided articles on the use of the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether that were published in the scientific literature. This real-world evidence demonstrates the safety and additional value of using the NaviCam Stomach Capsule and NaviCam Tether as part of the NaviCam stomach procedure (MCCE). Also included in a meta-analysis of esophageal and stomach examination times from clinical studies to show the combined examination time is well within the capsule battery life so both examinations may be completed satisfactorily.

9. CONCLUSION

The NaviCam Stomach Capsule and NaviCam Tether is an optional accessory to the NaviCam Capsule Endoscope System and the NaviCam Xpress Stomach Capsule Endoscope System which aims to supplement and augment the performance of the NaviCam Capsule by allowing the physician to control its downwards speed when moving through the esophagus. The NaviCam Stomach Capsule and NaviCam Tether does not affect the indications and performance of its parent devices, NaviCam Capsule Endoscope System and the NaviCam Xpress Stomach Capsule Endoscope System, and does not pose any new risks to the patient as demonstrated by the use of the device in clinical settings.