May 4, 2021

AnX Robotica Corp
Shoshana (Shosh) Friedman
VP of Quality and Regulatory Affairs
1047 Serpentine Lane
Pleasanton, CA 94566

Re: K203192
Trade/Device Name: NaviCam Xpress Stomach Capsule Endoscope System
(NaviCam Xpress Stomach System)
Regulation Number: 21 CFR 876.1310
Regulation Name: Magnetically maneuvered capsule endoscopy system
Regulatory Class: II
Product Code: QKZ
Dated: March 24, 2021
Received: March 26, 2021

Dear Shoshana (Shosh) Friedman:

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, 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)*

K203192

Device Name

NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System)

Indications for Use *(Describe)*

The NaviCam Xpress Stomach System 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
NaviCam Xpress Stomach System
510(k) Number K203192

1. SUBMITTER

Applicant's Name:
AnX Robotica, Corp.
1047 Serpentine Lane (Suite 100)
Pleasanton, CA 94566
Nazareth, Israel
Phone: (925) 202-2247
Fax: (925) 201-3852

Primary Contact:
Shoshana (Shosh) Friedman
Senior Regulatory Affairs Consultant
Phone: (704) 430-8695
s.friedman@promedoss.com

2. DATE PREPARED 04/19/2021

3. DEVICE

Trade Name:
NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System)

Classification Code: **Name:** Magnetically maneuvered capsule endoscopy system
Product Code: QKZ
Regulation No: 21 CFR 876.1310
Class: II
Classification Panel: Gastroenterology/Urology

4. PREDICATE DEVICES

NaviCam Capsule Endoscope System with NaviCam Stomach Capsule (NaviCam Stomach System) initially granted the De-Novo submission under DEN190037.

5. DEVICE DESCRIPTION

The NaviCam Xpress Stomach System is a 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 (AKEM-11SW) for obtaining images.
2. Data recorder (AKR-1) for logging image data.
3. Locator (AKS-1) for turning on the capsule and for determining if the capsule is still in the body.

4. Controller (NaviEC-2000) 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. INDICATIONS FOR USE

The NaviCam Xpress Stomach System 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.

7. SUBSTANTIAL EQUIVALENCE

The NaviCam Xpress Stomach System is substantially equivalent to the predicate device based on the following:

Indications for Use
The intended use of the proposed system and the cleared system are identical.

Technology
The purpose of this submission is the modification of the NaviCam Controller for the purpose of making a compact version called Xpress and, consequently, implementation of several changes to the system that were needed to enable this modification.
Main changes that were implemented include:

- Integration of the console into the controller and addition of a touch screen.
- Separation of the image review function from the main system software to a dedicated review software, named ESView, that can run on PC/laptop.
- Removal of the examination bed allowing the use of standard examination beds that comply with the provided specifications.
- Addition of anti-collision sensor to prevent colliding with a person or object and replacement of the motor with a safer one.

Operation
The NaviCam procedure with the NaviCam Xpress System was slightly adjusted to accommodate the changes mentioned above.

Discussion
The NaviCam Xpress Stomach System has substantially similar indications and contraindications, technological and performance characteristics, and operational characteristics as these of the NaviCam Stomach System predicate device. Any differences between the two systems have been addressed through testing.

8. PERFORMANCE DATA

Bench/In-Vitro Testing
The NaviCam Xpress Stomach System successfully passed the following test:

Test	Purpose
NaviCam Xpress Controller System Test	To verify that the NaviCam Xpress Controller meets the performance requirements stated in its specifications and implements the software functions stated in its User Manual.
NaviCam Xpress System Magnetic Field Intensity Range Test	To verify that the magnetic field intensity range of NaviCam Xpress meets its specifications when used with examination beds/tables provided by the users.
NaviCam Xpress Controller Mechanical Motion Range Test	To verify that the mechanical motion range of the NaviCam Xpress Controller meets its specifications.
Influence of Titanium Clips on the Controller's Ability to Control the Capsule and the Packet Loss Rate During Communication	To test whether the data communication of the capsule will be affected when the titanium clip, the capsule and the data recorder are in the magnetic field of the controller, and whether the position of the titanium clip will change when the magnetic head rotates.

Additionally, the NaviCam Xpress Stomach System was tested for compliance with the following standards:

- IEC 60601-1 Edition 3.1 (2012)
- ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21
- CAN/CSAC22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03;
- EN 60601-1:2006 + A1:2013 + A12:2014
- AAMI IEC 60601-1-2:2014
- EN 60601-1-2:2015

The system was found to comply with all applicable requirements of these standards.

9. CONCLUSION

AnX Robotica, Corp. believes that the NaviCam Xpress Stomach System is substantially equivalent to its predicate device, the NaviCam Stomach System. It has substantially equivalent indications for use, technological, performance characteristics as well as operational characteristics, and therefore does not introduce any new safety or effectiveness concerns.