May 22, 2020

AnX Robotica, Inc.
% Shoshana Friedman
Senior Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, NC 28269

Re: DEN190037
Trade/Device Name: NaviCam Capsule Endoscope System
with NaviCam Stomach Capsule
Regulation Number: 21 CFR 876.1310
Regulation Name: Magnetically maneuvered capsule endoscopy system
Regulatory Class: II
Product Code: QKZ
Dated: August 12, 2019
Received: August 13, 2019

Dear Shoshana Friedman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule, a prescription device under 21 CFR Part 801.109 with the following indications for use:

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

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule, and substantially equivalent devices of this generic type, into Class II under the generic name magnetically maneuvered capsule endoscopy system.

FDA identifies this generic type of device as:

> **Magnetically maneuvered capsule endoscopy system**. A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 13, 2019, FDA received your De Novo requesting classification of the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Infection	Reprocessing validation Sterilization validation Labeling
Adverse tissue reaction	Biocompatibility evaluation
Aspiration of capsule leading to injury	Labeling
Tissue damage	Clinical performance testing Labeling
Equipment malfunction leading to injury	Electrical, thermal, and mechanical safety testing Software validation, verification, and hazard analysis Human factors testing Non-clinical performance testing Shelf life testing Labeling

Identified Risk	Mitigation Measures
Interference with other devices (e.g., interference with image acquisition, patient information compromised, and ferromagnetic implants in users and patients)	Electromagnetic compatibility testing Software validation, verification, and hazard analysis Non-clinical performance testing Labeling
Failure to visualize areas of the stomach and duodenum leading to inadequate treatment	Clinical performance testing Non-clinical performance testing Labeling
Failure to excrete the capsule due to an obstruction resulting in abdominal pain, nausea, and vomiting	Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the magnetically maneuvered capsule endoscopy system is subject to the following special controls:

1. Clinical performance testing with the device under anticipated conditions of use must evaluate visualization of the intended region and document the adverse event profile.

2. Non-clinical testing data must demonstrate the optical, mechanical, and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested, and detailed protocols must be provided for each test:
   i. A bite test must be performed to ensure that the capsule can withstand extreme cases of biting.
   ii. A pH resistance test must be performed to evaluate integrity of the capsule when exposed to a physiological relevant range of pH values.
   iii. A battery life test must be performed to demonstrate that the capsule's operating time is not constrained by the battery capacity.
   iv. A shelf life test must be performed to demonstrate that the device performs as intended at the proposed shelf life date.
   v. Optical testing must be performed to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, geometric distortion, signal to noise ratio, dynamic range, and image intensity uniformity.
   vi. A color performance test must be performed to compare the color differences between the input scene and output image.
   vii. A photobiological safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible and near-infrared ranges, as appropriate. A mitigation analysis must be provided.
   viii. Performance testing must demonstrate that the viewing software clearly presents the current frame rate, which is either adjustable manually by the user or automatically by the device. Testing must demonstrate that the viewing software alerts the user when the video quality is reduced from nominal due to imaging data communication or computation problems.
   ix. A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the receiver. This test must include controlled signal attenuation for simulating a non-ideal environment.

x. Magnetic field strength testing characterization must be performed to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

3. Software validation, verification, and hazard analysis must be provided.

4. Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility (EMC) testing must be performed.

5. The patient-contacting components of the device must be demonstrated to be biocompatible.

6. Performance data must validate the reprocessing instructions for the reusable components of the device.

7. Performance data must demonstrate the sterility of any device components labeled sterile.

8. Human factors testing must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.

9. Clinician labeling must include:
   i. Specific instructions and the clinical and technical expertise needed for the safe use of the device;
   ii. A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;
   iii. The patient preparation procedure;
   iv. A detailed summary of the device technical parameters;
   v. Magnetic field safe zones;
   vi. A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet;
   vii. Reprocessing instructions for reusable components;
   viii. Shelf life for single use components; and
   ix. Use life for reusable components.

10. Patient labeling must include:
   i. An explanation of the device and the mechanism of operation;
   ii. The patient preparation procedure;
   iii. A brief summary of the clinical study; and
   iv. A summary of the device- and procedure-related complications pertinent to use of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the magnetically maneuvered capsule endoscopy system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Stephanie Cole at 301-796-8587.

Sincerely,

Benjamin R. Fisher, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health