December 2, 2022

ANKON Technologies Co., Ltd.
% Shoshana Friedman
Senior Regulatory Affairs Consultant
ProMedoss Inc
3521 Hatwynn Road
Charlotte, NC 28269

Re: K221590
Trade/Device Name: NaviCam Small Bowel Capsule Endoscopy System
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: Class II
Product Code: NEZ
Dated: November 2, 2022
Received: November 2, 2022

Dear Shoshana 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 -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)*

K221590

Device Name

NaviCam Small Bowel Capsule Endoscopy System

Indications for Use *(Describe)*

The NaviCam Small Bowel Capsule Endoscopy System is intended for visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.

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 Small Bowel Capsule Endoscopy System
510(k) NumberK221590

1. SUBMITTER

Applicant's Name:
ANKON Technologies Co., Ltd.
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Senior Regulatory Affairs Consultant
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2. DATE PREPARED

11/20/2022

3. DEVICE

Trade Name: NaviCam Small Bowel Capsule Endoscopy System

Classification:
Name: System, Imaging, Gastrointestinal, Wireless, Capsule
Product Code: NEZ
Regulation No: 876.1300
Class: II
Classification Panel: Gastroenterology/Urology

4. PREDICATE DEVICES

- **Primary Predicate Device**: Given PillCam (SB3) Endoscopy System cleared under Kl23864 (hereafter referred to as "PillCam SB3").
- **Reference Device**: NaviCam Capsule Endoscope System with NaviCam Stomach Capsule (also referred to as "NaviCam Stomach System") granted De-Novo under DEN190037

5. DEVICE DESCRIPTION

The NaviCam Small Bowel Capsule Endoscopy System is an endoscopic capsule imaging system intended to obtain images of the small bowel. It is comprised of the following components:

[1.] **Capsule (AKES-11SW, AKES-11SI):** The disposable, ingestible NaviCam Small Bowel Capsule is designed to acquire video images during the natural propulsion

through the GI tract. The capsule transmits the acquired images via an RF communication channel to the NaviCam Data Recorder located outside the body.

[2.] **Data recorder (AKR-1, AKRI-1):** The Data Recorder is an external receiving and recording unit that receives and stores the acquired images from the capsule.

[3.] **ESView Software:** The ESView is a software application for processing, analyzing, storing, and viewing the acquired images collected from the NaviCam Data Recorder to create a video of the images. The software also includes a reporting function to create detailed clinical reports and a capsule endoscopy atlas.

[4.] **Locator:** The Locator is a handheld device that is used to turn the NaviCam Capsule on. It is also used for determining if the capsule is still in the body when the patient is not sure whether he/she expelled it.

6. INDICATIONS FOR USE

The NaviCam Small Bowel Capsule Endoscopy System is intended for visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.

7. SUBSTANTIAL EQUIVALENCE

The NaviCam Small Bowel Capsule Endoscopy System is substantially equivalent to the predicate devices based on the following:

Indications and Contraindications
The indications for use of the NaviCam Small Bowel Capsule Endoscopy System are included within the indications for use of the PillCam SB3 Capsule Endoscopy System primary predicate device. The contraindications for use of the NaviCam Small Bowel Capsule Endoscopy System are the same as these of the PillCam SB3 Capsule Endoscopy System

Technology
The capsule, data recorder, and software of the NaviCam Small Bowel Capsule Endoscopy System are substantially equivalent to these of the PillCam SB3 Capsule Endoscopy System primary predicate system.
The capsule, data recorder, and locator of the NaviCam Small Bowel Capsule Endoscopy System are also substantially equivalent to these of the reference device, the NaviCam Stomach System.

Performance
The performance of the NaviCam Small Bowel Capsule Endoscopy System was compared to this of the PillCam SB3 Capsule Endoscopy System primary predicate device and found to be substantially equivalent.

Conclusion
The NaviCam Small Bowel Capsule Endoscopy System has substantially similar indications and contraindications, technological, and performance characteristics as these of the predicate and reference devices. Any minor differences that may exist do not affect its safety and effectiveness when used as intended.

8. PERFORMANCE DATA

The NaviCam Small Bowel Capsule Endoscopy System was tested in accordance with the FDA guidance titled "Ingestible Telemetric Gastrointestinal Capsule Imaging System - Final Class II Special Controls Guidance Document for Industry and FDA".

Bench/In-Vitro Testing

The NaviCam Small Bowel Capsule Endoscopy System successfully passed the following test:

Test	Purpose
Biting Test	To demonstrate that the NaviCam SB capsule can withstand applied forces as may occur in case of accidental biting.
Angular Resolution Test	To measure the MTF using ISO 12233 slanted edge methodology, and to provide a new angular resolution method using LEDs in the capsule.
Temperature Safety Test	To test the temperature change during NaviCam SB capsule operation.
pH Test	To evaluate the integrity of the NaviCam SB capsule during exposure to simulated condition of extreme pH levels.
Image Intensity Uniformity	To evaluate the intensity uniformity of the NaviCam SB capsule image.
Image Frame Rate Test	To demonstrate that the higher frame rate of NaviCam SB capsule image provides good transmission property.
Geometric Distortion Test	To determine geometric distortion of the NaviCam SB capsule and provide the local magnification of the image.
Field of View (FOV) Test	To determine the FOV value of the NaviCam SB capsule.
Battery Life Test	To demonstrate that the battery life of the NaviCam SB capsule lasts at least 8 hours and captures over 57500 images.
Image Resolution Test	To test the image resolution of the NaviCam SB capsule.
Magnetic Field Test	To measure the maximum value of magnetic flux density on the surface of the NaviCam SB capsule, the magnetic flux density on the non-optical bottom of the capsule, and to determine the magnetic field safety distance of the capsule.
DOV Test	To measure the MTF in air and underwater at different distances within the claimed DOV range using ISO 12233 slanted edge methodology and angular resolution method.
Color and Gray Scale Test	To evaluate the optical performance of the NaviCam SB capsule.
Data Integrity Test	To test the data transmission between the capsule through the data recorder and the ESView software.

The NaviCam Small Bowel Capsule System was tested for compliance with the following standards and regulations:

- IEC 60601-1:2005+A1:2012 / EN 60601-1:2006 + A1:2013 + A12:2014
- 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/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03.

- IEC 60601-1-11:2015. ANSI/AAMI HA60601-1-11: 2015
- CAN/CSA-C22.2 No. 60601-1-11: 15
- IEC 60601-1-2:2014
- IEC 61000-3-2:2014
- IEC 61000-3-3:2013
- IEC 62471 (1st edition 2006-07)
- IEC 62133:2012; IEC 62133-2:2017
- ANSI C63.27-2017
- UL 1642:2020
- 47 CFR Part 15

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

Clinical Data

The NaviCam Small Bowel Capsule Endoscopy System was evaluated in a prospective study, comparing its performance to that of the FDA cleared PillCam SB3 Capsule Endoscopy System (NCT05086471).

In this prospective clinical study, the NaviCam Small Bowel Capsule Endoscopy System and PillCam SB3 Capsule Endoscopy System had a diagnostic Overall Percent Agreement rate of 89.66% (81.50%, 94.46%), and an overall percent agreement Kappa of 0.6652 (0.4653, 0.8652). The results of this comparative study demonstrate that the NaviCam Small Bowel Capsule Endoscopy System performs similarly to the PillCam SB3 Capsule Endoscopy System and provides an effective non-invasive method for the detection of small bowel diseases.

9. CONCLUSION

ANKON Technologies Co., Ltd. believes that the NaviCam Small Bowel Capsule Endoscopy System is substantially equivalent to its primary predicate device, the Given PillCam (SB3) Endoscopy System and its reference device, the NaviCam Stomach System. It has substantially equivalent indications and contraindication, technological characteristics, and performance characteristics to these of the primary and reference systems, and therefore does not introduce any new safety or effectiveness concerns.