December 16, 2024

Ankon Technologies Co., Ltd
% Shoshana Friedman
Senior RA Consultant
ProMedoss, Inc
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: DEN230027
Trade/Device Name: NaviCam ProScan
Regulation Number: 21 CFR 876.1540
Regulation Name: Gastrointestinal capsule endoscopy analysis software device
Regulatory Class: Class II
Product Code: QZF
Dated: April 14, 2023
Received: April 14, 2023

Dear Shoshana Friedman:

This letter corrects our previous classification order, dated December 12, 2023, to clarify the postmarket surveillance requirement.

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 ProScan, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> NaviCam ProScan is an artificial intelligent (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through review of the entire video, as clinically appropriate. ProScan also assists small bowel capsule endoscopy reviewers in identifying the digestive tract location (oral cavity and beyond, esophagus, stomach, small bowel) of the image in adults. This tool is not intended to replace clinical decision making.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NaviCam ProScan, and substantially equivalent devices of this generic type, into Class II under the generic name gastrointestinal capsule endoscopy analysis software device.

FDA identifies this generic type of device as:

Gastrointestinal capsule endoscopy analysis software device. A gastrointestinal capsule endoscopy analysis software device is used to analyze pre-recorded capsule endoscopy videos of the gastrointestinal tract that are suspected of containing lesions. This device uses software algorithms to identify images and areas of interest as outputs to aid the clinician in analyzing suspected lesions, for clinician review of device outputs. The device may contain hardware to support interfacing with a capsule imaging system.

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 April 14, 2023, FDA received your De Novo requesting classification of the NaviCam ProScan. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NaviCam ProScan 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 ProScan 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:

Risks to Health	**Mitigation Measures**
Algorithm failure leading to: • False positive resulting in unnecessary patient treatment; or • False negatives resulting in delayed or lack of patient treatment; or • Missed analysis due to misclassification of tract site resulting in delayed treatment	Clinical performance testing Postmarket surveillance Standalone algorithm performance testing Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing Electrical safety, thermal safety, and mechanical safety testing Labeling
False positive or false negative due to user overreliance on the device	Clinical performance testing Postmarket surveillance Labeling

In combination with the general controls of the FD&C Act, the gastrointestinal capsule endoscopy analysis software device is subject to the following special controls:

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended when used to analyze data from the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required. The following must be met:
   (i) Validation must use a clinical test dataset acquired from a representative patient population. Data must be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment. Establishment of ground truth must be clinically justified. Study protocols must include a description of the process(es) for determining ground truth of training and test datasets;
   (ii) Objective performance measures (e.g., patient-level, lesion-level, and image-level data) with corresponding confusion matrices and statistical analyses must be reported with relevant descriptive or developmental performance measures. Summary level demographic information for study subjects and clinicians and sub-group analyses must be provided for each study site, relevant demographic sub-groups, and acquisition systems;
   (iii) The test dataset must be from sites that are different from sites used in training or development of the model; and
   (iv) Adverse events must be reported.
(2) Performance testing of the algorithm (i.e., standalone performance of the device itself, in the absence of any interaction with a clinician) must be provided.
(3) Software verification, validation, and hazard analysis must be provided. Software description must include a detailed, technical description including the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, the associated inputs and outputs, and mapping of the software architecture.
(4) Performance data must demonstrate electromagnetic compatibility, electrical safety, mechanical safety, and thermal safety for any hardware components of the device.
(5) Labeling must include:
   (i) Warnings to avoid overreliance on the device, including that findings, or the lack thereof, should be reviewed by the clinician; that the device is not intended to be used as a standalone diagnostic device; and that the device does not replace clinical decision-making;
   (ii) A summary of the performance testing methods, including tested hardware, tested/supported patient population, results of the performance testing for tested performance measures/metrics with statistical analysis, summary-level descriptions of patient and clinician demographics and associated subgroup analyses for training and test datasets; and
   (iii) According to the timeframe specified in any postmarket surveillance protocol approved by FDA to satisfy the requirements in paragraph (1) of this section, a detailed summary of the postmarket surveillance data must be provided, including updates to the labeling to accurately reflect device performance based upon data collected during the postmarket surveillance experience.

In order to satisfy special control (1) above, FDA has determined that you must collect and report postmarket surveillance data acquired under anticipated conditions of use to demonstrate the performance of the

NaviCam ProScan lesion detection feature with physician input in the intended patient population, at the lesion-level, image-level, and patient-level, and demonstrate the performance of the NaviCam ProScan anatomic tract site recognition function at the object-level.

FDA expects that the postmarket clinical validation performance testing will address the performance of NaviCam ProScan (with physician input), as compared to a standard unassisted read using a clinically justified ground truth, on:

- Lesion-level, image-level, and patient-level analysis for lesion detection feature, including relevant FROC (free response receiver operating characteristic) analysis, ROC (receiver operating characteristic) analysis, sensitivity, specificity, and confusion matrices, as applicable and provide additional analysis for these endpoints for ProScan outputs (before physician input); and

- Object-level ROC analysis for anatomic tract site recognition function, including sensitivity, specificity, and confusion matrices, as applicable.

Within 30 days of receipt of this corrected order, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve your study protocol within 60 days of this corrected order. Your submission should be clearly labeled as a "De Novo Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of postmarket study protocol approval, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the new enrollment postmarket study as follows:

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the protocol approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every three (3) months in addition to your periodic postmarket surveillance progress reports, until enrollment has been completed or FDA notifies you otherwise.
- Submit the final postmarket surveillance report three (3) months from study completion (i.e., last subject's last follow-up date).

Additionally, to meet special control (5)(iii), you must update device labeling with the results produced by

postmarket clinical validation performance testing within the timeframe specified in the approved postmarket surveillance protocol.

Each postmarket surveillance report should be submitted to the Agency as specified below, identified as a "De Novo Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your 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 gastrointestinal capsule endoscopy analysis software device 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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

De Novo Postmarket Surveillance
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning the contents of the letter, please contact Anthony C Lee at 240-402-5935.

Sincerely,

Kellie B. Kelm -S

Kellie B. Kelm, Ph.D.
Acting Office Director
OHT3: Office of GastroRenal, ObGyn,
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