Build Correspondence | Convert to PDF

November 22, 2022

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

Re: Q221569
Trade/Device Name: NaviCam Tether Accessory
Evaluation of Accessory Classification Under Section 513(f)(6) - Accessory Classification Request
Regulation Number: 21 CFR 876.1305
Regulation Name: Tether accessory for use in the gastrointestinal tract
Regulatory Classification: Class II
Product Code: QUN
Dated: June 2, 2022
Received: June 7, 2022

Dear Tim Thomas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification Request for classification of the NaviCam Tether Accessory, a prescription device under 21 CFR 801.109 that is intended to aid the capsule to visualize the esophagus (not magnetically maneuvered) prior to the capsule's release into the stomach for a stomach capsule endoscopy.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the NaviCam Tether Accessory, and substantially equivalent devices of this generic type, into class II under the generic name Tether accessory for use in the gastrointestinal tract.

FDA identifies this generic type of device as:

> **Tether accessory for use in the gastrointestinal tract**. *Identification.* A non-powered, detachable, flexible device used to maneuver a swallowed parent device, such as a capsule, in the upper gastrointestinal tract.

Section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017 and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other

device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

FDA received your Accessory Classification request on June 7, 2022 to classify the NaviCam Tether Accessory into class II under section 513(f)(6)(C) of the FD&C Act. In order to classify the NaviCam Tether Accessory into class I or II, the proposed class must 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 Accessory Classification request, FDA has determined that the NaviCam Tether Accessory intended to aid the capsule to visualize the esophagus (not magnetically maneuvered) prior to the capsule's release into the stomach for a stomach capsule endoscopy can be classified in class II with the establishment of special controls. FDA has determined 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Infection	Sterilization validation Labeling
Adverse tissue reaction	Biocompatibility evaluation
Aspiration of tether or capsule leading to injury	Non-clinical performance testing Labeling

Injury from equipment malfunction or use error	Usability assessment Non-clinical performance testing Shelf-life testing Labeling
Failure to position capsule in intended areas leading to inadequate treatment	Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the Tether accessory for use in the gastrointestinal tract is subject to the following special controls:

1. Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate:
    a. Ease of ingestion.
    b. Ease of removal.
    c. Demonstration that the tether, when used with a parent device, allows the parent device to function per the parent device's intended use.
    d. Adverse events during and following the use of the tether.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including:
    a. A bite test must be performed to ensure that the tether can withstand extreme cases of biting.
    b. A pH resistance test must be performed to evaluate integrity of the tether when exposed to a physiological relevant range of pH values for the period of time that the device will be used.
    c. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
    d. Mechanical integrity must be evaluated to characterize the strength of the device system when subjected to mechanical forces that may be expected during clinical usage.
    e. Force testing must be performed to ensure the parent device can remain connected to the tether during use and can be detached from the tether when needed.

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

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

5. Usability assessment must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.

6. Clinician labeling must include:
    a. Specific instructions and the recommended training for safe use of the device;

b. A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;
c. The patient preparation procedure;
d. A detailed summary of the device technical parameters; and
e. Shelf life.

7. Patient labeling must include:
   a. An explanation of the device and the mechanism of operation;
   b. The patient preparation procedure;
   c. A brief summary of the clinical study; and
   d. 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.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and, if applicable, 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 is on file in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and is available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Sivakami Venkatachalam at 301-796-9103 or Sivakami.Venkatachalam@fda.hhs.gov.

Sincerely,

/s/

Courtney H. Lias, 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