May 4, 2021

CapNostics, LLC
Martin von Dyck
President & CEO
9724 Colts Neck Lane
Concord, NC 28027

Re: K203450
Trade/Device Name: EsophaCap Swallowable Cellular Retrieval Device
(changed from Cell-Mata)
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOX
Dated: November 13, 2020
Received: November 23, 2020

Dear Martin von Dyck:

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)*
K203450

Device Name
EsophaCap® Swallowable Cellular Retrieval Device

Indications for Use *(Describe)*
The gathering and recovery of cells and cellular material from the mucosa in the esophagus for cytological and histological analyses.

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

General Information:

Date of Submission: November 13, 2020

Submitter / Owner of the 510(K):

CapNostics, LLC.
9724 Colts Neck Lane
Concord, NC 28027 USA

Contact Person:

Martin von Dyck
President & CEO
Phone: (610) 442-1363
E-mail: mvondyck@capnostics.com

Trade/Proprietary Name of Device:

Trade Name:	EsophaCap® Swallowable Cellular Retrieval Device
Common Name:	Mass cytology cellular retrieval device
Classification Name:	Esophagoscope (Flexible or Rigid)
Regulation Number:	21CFR 874.4710
Product Code:	EOX
Device Panel:	Ear, Nose and Throat Devices
Device Classification:	Class II

Legally Marketed Predicate Devices for Claimed Equivalency:

a) K934193: Cell-Mate™ Mass Cytology -Cellular Retrieval System

b) K142695, K152794 and K181020: Cytosponge™ Cell Collection Device

Note: The CytoSponge device in the original 510(k) submission (K142695) used the Cell-Mate (K934193) as the predicate device.

Device Description:

The EsophaCap® Swallowable Cellular Retrieval Device is a non-sterile, non-endoscopic, single-use Esophageal cell sampling device. The EsophaCap® is composed of an open-cell polyether polyurethane foam sphere attached to a polyester tether/stylus and tether cap. The open-cell foam sphere ranging in diameter sizes from 20 mm to 35mm is compressed and encapsulated within a vegetable (hypromellose (HPMC)) capsule. When swallowed the EsophaCap® capsule dissolves releasing the foam sphere. The foam sphere expands to form a cytology and cellular retrieval device that allows a circumferential "bottle brush" collection using the expanded "open cell" foam sphere. The radiopaque polyester tether/stylus is used to slowly withdraw the foam sphere through the esophagus and then to subsequently retrieve the foam sphere with the cellular sample.

Indications for Use:

The gathering and recovery of cells and cellular material from the mucosa in the esophagus for cytological and histological analyses.

Technological Characteristics of the Subject Device Compared to the Predicate Devices:

The EsophaCap® Swallowable Cellular Retrieval Device is substantially equivalent to the legally marketed predicate Cell-Mate™ Mass Cytology Cellular Retrieval System cleared under K934193. The substantial equivalence is in terms of intended use/indications of use, target patient population, anatomical locations, method of operation, operating instructions, and single use.

The technological differences are that this subject device is:

a. non-sterile, while the predicate device is provided sterile;
b. there is a change in the dissolvable capsule material from animal based gelatin to a vegetable capsule;
c. shelf-life (for the 10 pore per inch foam sphere);
d. an additional foam porosity has been added;
e. an additional smaller foam sphere diameter;
f. a smaller capsule has been added;
g. the tether cap location has been moved
h. the tether/stylus was shortened;
i. the labeling/IFU have been updated to reflect the preceding changes.

The EsophaCap® Swallowable Cellular Retrieval Device is also substantially equivalent to the legally marketed Cytosponge™ Cell Collection Device cleared under K142695, K152794, and K181020. The substantial equivalence is in terms of intended use/indications of use, anatomical locations, method of operation, operating instructions, single use, non-sterile, foam porosity, and vegetable capsule.

Testing Performance Data:

The EsophaCap® Swallowable Cellular Retrieval Device performance testing consisted of bench testing, biocompatibility testing and user input. The bench testing included: dissolution testing, and tether /stylus tensile testing, and tether/stylus length test.

Conclusion:

CapNostics LLC, considers the EsophaCap® Swallowable Cellular Retrieval Device to be substantially equivalent to the legally marketed predicates: Cell-Mate™ Mass Cytology Cellular Retrieval System (K934193) and Cytosponge™ Cell Collection Device (K142695, K152794, and K181020). Based upon the results of performance testing the design modifications to the EsophaCap® Swallowable Cellular Retrieval Device raises no new safety and effectiveness questions.