August 16, 2018

Covidien, llc.
Rachel Silva
Principal Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K181020
Trade/Device Name: Cytosponge Cell Collection Device
Regulation Number: 21 CFR§ 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Regulatory Class: II
Product Code: EOX
Dated: July 27, 2018
Received: July 30, 2018

Dear Rachel Silva:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey W. Cooper -S
2018.08.16 15:43:58
-04'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181020

Device Name

Cytosponge Cell Collection Device

Indications for Use *(Describe)*

The Cytosponge Cell Collection Device is indicated for use in the collection and retrieval of surface cells 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.

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510(k) Summary

510(k) Number: K181020

Submitter's Name and Address:
Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person:
Rachel Silva
Principal Regulatory Affairs Specialist
Phone: (408) 328-7359
Fax: (408) 328-7359

Date Prepared: July 3, 2018

Name of Device:
Proprietary Name: Cytosponge™ Cell Collection Device
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Classification Panel: Ear, Nose & Throat Devices
Device Regulation: 21 CFR 874.4710, Class II
Product Code: EOX

Establishment Registration Number, Owner/Operator Number:
Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Predicate Device(s):
K152794 Cytosponge™ Cell Collection Device by Covidien llc (Primary predicate)
K142695 Cytosponge™ Cell Collection Device by Covidien llc (Reference predicate)

Device Description:
The Cytosponge™ Cell Collection Device is a non-sterile, single-use device. The Cytosponge™ Cell Collection Device consists of a clear, size 00 vegetable-material-derived capsule which holds a 30mm compressed spherical sponge inside of the capsule. The capsule containing the sponge is attached to a silicone-coated braided polyester suture. The suture is attached and secured to a retainer card via an ABS plug. The capsule is swallowed and dissolves in the stomach thereby releasing the self-expanding sponge. The sponge is then retrieved from the stomach using the attached suture. During the retrieval process, the sponge collects cells from the outer layer of esophageal tissue.

Indications for Use:
The Cytosponge™ Cell Collection Device is indicated for use in the collection and retrieval of surface cells in the esophagus for cytological and histological analyses.

Technological Characteristics of the Device Compared to Predicate Device
The Cytosponge™ Cell Collection Device has the same indications for use, principle of operation, and single use disposition as the predicate device Cytosponge™ Cell Collection Device cleared under K142695 and K152794. There also have been no material changes for the subject device from the predicate device. The technological differences are that the subject device is non-sterile, has a change in porosity of the sponge, and thicker suture diameter.

Performance Data
Performance testing for the Cytosponge™ Cell Collection Device consisted of bench functional testing, shelf life testing, biocompatibility testing and user validation. Functional testing included compression testing, diameter measurement testing, laceration testing, dissolution and tensile testing. Results of performance testing demonstrate performance equivalence for the Cytosponge™ Cell Collection Device when evaluated against the predicate device.

Conclusion
Covidien llc considers the Cytosponge™ Cell Collection Device to be substantially equivalent to the legally marketed predicate device Cytosponge™ Cell Collection Device (K142695 and K152794). Test results provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.