DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 12, 2016

Covidien LLC
Saket Bhatt
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, MA 02048

Re: K152794
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: March 8, 2016
Received: March 9, 2016

Dear Saket Bhatt,

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152794

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.

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510(k) Summary

Submitter Information

Name:	Covidien llC
Address:	15 Hampshire Street Mansfield, MA 02048
Name of contact person:	Saket Bhatt Manager, Regulatory Affairs 540 Oakmead Parkway Sunnyvale, CA 94085
Phone:	(408) 328-7357
Fax number:	(408) 328-7357 (same as phone)
Date prepared:	April 8, 2016
Establishment Registration:	3004904811
Owner/Operator Number:	1282497
Legal Manufacturer:	Covidien, llc 15 Hampshire Street Mansfield, MA 02048
Manufacturing Facility:	Covidien IIc, GI Solutions 540 Oakmead Parkway Sunnyvale, CA 94085
Name of Subject Device:	Cytosponge™ Cell Collection Device
Trade or proprietary name:	Cytosponge™ Cell Collection Device
Classification Name:	Esophagoscope (Flexible or Rigid)
Classification:	Class II
Classification panel:	Gastroenterology/Urology Ear Nose & Throat Panel
Regulation:	21 CFR 874.4710
Product Code:	EOX

Legally marketed devices to which equivalence is claimed:	Cytosponge™ Cell Collection Device (K142695)
Reason for 510(k) Submission:	The purpose of this 510(k) is to notify the Agency of an expanded indication and the addition of clinical information to the labeling resulting from a Covidien clinical study using the Cytosponge™ Cell Collection Device. Additionally the warning of platelet inhibiting agents was moved and combined with the contraindications of antithrombotic drugs that cannot be temporarily discontinued.
Device description:	The subject device Cytosponge™ Cell Collection Device is a sterile single-use device. The Cytosponge™ Cell Collection Device consists of a clear, size 00 vegetable-material-derived capsule, which holds a 30mm spherical sponge inside of the capsule. The capsule containing the sponge is attached to silicone-coated braided polyester suture. The suture is attached and secured to a retainer card via an ABS plug. The Cytosponge™ Cell Collection Device consists of a swallowable capsule, which dissolves in the stomach, releasing a self-expandable sponge. The sponge is then retrieved from the esophagus using an attached cord; during the retrieval process, the sponge collects cells from the outer layer of esophageal tissue
Intended use:	The Cytosponge™ Cell Collection Device is intended for use in the collection and retrieval of surface cells in the esophagus.
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 Device Compared to Predicate Device:	As the subject of this submission is an expanded indication and labeling changes, the Cytosponge™ Cell Collection Device has identical technological characteristics is to the legally marketed predicate device cleared by the agency under K142695. There have been no design or material changes to the Cytosponge™ device cleared on November 26, 2014. There have been minor changes to the package insert that did not require a submission and were documented via Letter to File. The difference between the proposed Cytosponge™ Cell Collection Device and the predicate device (K142695) is an expanded indication and the addition of clinical information to the labeling resulting from a Covidien clinical study.

Summary of Clinical Tests Performed:	In a Covidien sponsored post-market study in a population of individuals with confirmed Barrett's esophagus (BE), sample adequacy was measured by the presence of columnar cells. For the purposes of this investigation, an adequate sample was one in which at least one group of columnar cell was present. No minimal size was required for a group; a group of columnar cells can consist of two cells that are clearly columnar. Sample adequacy was presented as a proportion of subjects who fulfilled this definition after up to two total administrations of the Cytosponge device. Sixty-eight subjects met the inclusion criteria for sample adequacy. Four out of sixty-eight samples were inadequate. Two of the four patients repeated the Cytosponge device swallow and met the criteria for sample adequacy. Sixty-four of sixty-eight Cytosponge samples were sample adequate after one administration. Sixty-six of sixty-eight Cytosponge samples or 97% were sample adequate after two administrations.
Performance data:	The subject Cytosponge™ Cell Collection Device is technologically identical to the cleared predicate device cleared by the agency under K142695. Accordingly, no performance testing was conducted.
Conclusion:	The clinical study demonstrates the Cytosponge™ Cell Collection Device may be used for cytological and histological analyses and is substantially equivalent to the predicate device.