January 19, 2024

Cyted Limited
℅ Matthew Burton
Strategic Development Director
IMed Consultancy Ltd
Bloxham Mill
Bloxham, Oxfordshire OX15 4FF
United Kingdom

Re: K233142
Trade/Device Name: EndoSign® Cell collection device (ES-CYT-102)
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOX
Dated: December 22, 2023
Received: December 22, 2023

Dear Matthew Burton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

for
Shani 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.

Submission Number *(if known)*

K233142

Device Name

EndoSign® Cell collection device (ES-CYT-102)

Indications for Use *(Describe)*

The EndoSign® Cell collection device is to be used for the collection of cells from the surface of the oesophagus for molecular, 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.

Cyted

510(k) Summary

EndoSign® Cell collection device

Submitter's Name and Address:
Cyted Ltd
22 Station Road
Cambridge
CB1 2JD
United Kingdom

Primary Contact/ Person:
Neha Goel
Chief Operating Officer
Phone: +44 1223 616421

Date prepared:
27 September 2023

Name of Device:

Trade/Proprietary Name:	EndoSign® 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

Legally Marketed Predicate Device:
K181020 Cytosponge™ Cell Collection Device by Covidien LLC.

Device Description:
The EndoSign® Cell collection device is to be used for the collection of cells from the surface of the oesophagus for molecular, cytological and histological analyses. It is a non-sterile low risk, transient use, minimally invasive, single use, oesophageal cell collection device designed for use by trained and qualified medical professionals. The device is composed of a clear, size 00 capsule made from vegetable-derived material. The capsule houses a 30mm compressed spherical sponge and is connected to a non-absorbable silicone-coated braided polyester thread, secured to a clear polycarbonate applicator. The patient swallows the capsule along with the bundled thread, and as it travels through the oesophagus, the capsule dissolves allowing the sponge to expand and release. The thread is then gently pulled to retrieve the sponge, which collects cells from the lining of the oesophagus as it is removed. The device is used to collect cell samples which are further analyzed for identification of disease biomarkers. The results of the test will be used to assess patients suspected

of oesophageal pathologies such as Barrett's oesophagus, oesophageal cancer, eosinophilic esophagitis, and other abnormalities.

Indication for Use:
The EndoSign® Cell collection device is to be used for the collection of cells from the surface of the oesophagus for molecular, cytological and histological analyses.

Technological Characteristics of the Device Compared to Predicate Device:
The **EndoSign® 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 K181020. There have been no material changes for the subject device from the predicate device. The technological differences are that the subject device uses an applicator instead of a roll card so the user does not have to put their fingers in the patient's mouth. The thread comes pre-bundled, so the user does not have to perform manual bundling prior to use. **EndoSign® Cell collection device** is suitable, in addition, for taking samples for molecular analyses.

Performance data:
Performance testing for the **EndoSign® Cell collection device** consisted of bench functional testing, performance and safety validation, and shelf life. Functional testing included dissolution, tensile strength, biocompatibility, manufacturing accuracy, dimensional reproducibility, sampling sufficiency, and usability/human factors testing. Results of performance testing demonstrate performance equivalence for the **EndoSign® Cell collection device** when evaluated against the predicate device.

Conclusion:
Cyted Ltd considers the **EndoSign® Cell collection device** to be substantially equivalent to the legally marketed predicate device Cytosponge™ Cell Collection Device (K181020). Test results provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use and that it is at least as safe and effective as the predicate device.