June 21, 2019

Lucid Diagnostics, Inc.
℅ Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K183262
Trade/Device Name: EsoCheck CCD Cell Collection Device
Regulation Number: 21 CFR§ 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and Accessories
Regulatory Class: II
Product Code: EOX
Dated: May 31, 2019
Received: May 31, 2019

Dear Janice M. Hogan:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

for
Shani P. Haugen, Ph.D.
Acting, Assistant Division 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183262

Device Name
EsoCheck CCD Cell Collection Device

Indications for Use *(Describe)*
The EsoCheck CCD Cell Collection Device is indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age and older.

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

Date Prepared:	May 31, 2019
Submitter:	Lucid Diagnostics, Inc.
Address:	One Grand Central Place, Suite 4600, New York, NY 10165
Phone:	(212) 949-4319
Fax:	(212) 634-7403
Contact Person:	Lishan Aklog, MD Executive Chairman
Trade Name/Proprietary Name:	EsoCheck™ CCD Cell Collection Device
Class:	II
Common Name:	Balloon Cell Collection Device
Classification/Name:	Esophagoscope (flexible or rigid) and accessories
Regulation:	21 CFR 874.4710
Product Code:	EOX
Classification Panel:	Gastroenterology/Urology
Predicate Devices (Legally marketed devices to which substantial equivalence is claimed):	Wilson-Cook Medical, Inc. Brandt Cytology Balloon™, K911588 (predicate device) Covidien/Medtronic Cytosponge™, K142695 (reference device) Hobbs Medical, Inc. Hobbs Medical Cytology Brush, K834402 (reference device)

I. Device Description:

The Lucid Diagnostics EsoCheck™ CCD Cell Collection Device is a sterile single-use disposable non-endoscopic balloon capsule catheter designed to collect and retrieve surface cells of the esophagus. The balloon capsule is attached to a catheter and swallowed with the balloon deflated and inverted. Once positioned, the balloon is inflated and withdrawn allowing its textured surface to swab the surface of the targeted segment of the esophagus, retrieving cells in the process. The balloon is then deflated, retracting it along with the retrieved cells on its surface into the capsule, where they are protected from dilution or contamination as the capsule is fully withdrawn from the patient. The balloon is cut from the capsule and placed in the desired specimen container. The specimen is then sent for diagnostic processing and analysis.

II. Principles of Operation:

The EsoCheck CCD Cell Collection Device has been designed as a non-endoscopic cell sampling device intended to be used in the esophagus to obtain surface cells from the esophageal mucosa for cytologic analysis. The EsoCheck CCD Cell Collection Device accomplishes the equivalent of other previously cleared balloon devices and endoscopic brush devices to obtain surface cells from the mucosal lining of the esophagus without the patient having to go through an endoscopic procedure. The distal balloon, smaller than an adult sized vitamin pill, is swallowed by the patient and tethered by a catheter. When the deflated balloon reaches the patients stomach it is inflated and withdrawn into the patient's

esophagus bringing the textured balloon surface in contact with the mucosal surface of the esophagus. With the balloon in the inflated position, it is manually withdrawn from the esophagus. This allows the textured surface on the balloon to swab the surface of the esophagus to collect the target cells. The cells then adhere to the balloon surface. Using simple syringe vacuum, the balloon is slowly deflated and inverted into the capsule and removed from the patient. Once the balloon and capsule are out of the patient, the balloon is slowly inflated to re-expose the textured surface that holds the cell sample, and the balloon is cut from the capsule and deposited in the desired specimen container for cytopathologic processing.

III. Indications for Use:

The EsoCheck CCD Cell Collection Device is indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age or older.

IV. Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device:

The Lucid Diagnostics EsoCheck CCD Cell Collection Device is substantially equivalent to the predicate Brandt Cytology Balloon by Wilson-Cook Medical, Inc. based on the intended use / indications for use, the population for use, anatomical location, the design, the basic principles of operation and single-use disposition. The predicate device, the Brandt Cytology Balloon, was cleared by FDA in 510(k) K911588 in 1992.

The EsoCheck CCD Cell Collection Device is substantially similar to the Covidien/Medtronic Cytosponge™ based on the intended use / indications for use, the population for use, anatomical location, the basic principles of operation and single-use disposition. Additionally, the EsoCheck CCD Cell Collection Device is also substantially similar to the Hobbs Medical, Inc. Hobbs Medical Cytology Brush with regard to surface cytological retrieval capability; the Hobbs Cytology Brush has decades of established performance.

V. Summary of the Nonclinical Tests Performed:

Nonclinical testing for the EsoCheck CCD Cell Collection Device consisted of:

1. Verification Testing:
    - Visual and Dimensional Inspection
    - Balloon Capsule Assembly Measurement
    - Droop Test
    - Balloon Inflation/Deflation Tests
    - Balloon Burst Tests
    - Balloon Inversion Tests
    - Bond Tests
    - Tensile Tests
    - GLP Animal Studies
2. Validation Testing:
    - Biocompatibility testing (ISO 10993)
    - Sterilization lot release testing (EO)
    - Packaging validation

- Shelf life testing
- User validation

VI. Conclusions:

Lucid Diagnostics, Inc. considers the EsoCheck™ CCD Cell Collection Device to be substantially equivalent to legally marketed predicate device, the Brandt Cytology Balloon™ by Wilson-Cook Medical, Inc. (K911588) and similar to the legally marketed reference devices, Covidien/Medtronic Cytosponge™ (K142695) and the Hobbs Medical Cytology Brush (K834402). The test results and compliance with applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.