February 24, 2023

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

Re: K230339
Trade/Device Name: EsoCheck Cell Collection Device
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: February 7, 2023
Received: February 7, 2023

Dear Kelliann Payne:

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,

Sivakami Venkatachalam -S

for
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)*
K230339

Device Name
EsoCheck Cell Collection Device

Indications for Use *(Describe)*
The EsoCheck Cell Collection Device is indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults and adolescents, 12 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)

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510(k) Summary

Lucid Diagnostics, Inc.'s EsoCheck™ Cell Collection Device

Submitter's Information and Date Prepared

Lucid Diagnostics
360 Madison Ave, Floor 25
New York, NY 10017
Phone: (216) 536-6527
Fax: (212) 634-7403
Contact Person: Deepika Lakhani

Date Prepared: February 6, 2023

Device Information

Trade Name: EsoCheck™ Cell Collection Device

Common or Usual Name: Balloon Cell Collection Device

Classification Name: Esophagoscope (flexible or rigid) and accessories
21 CFR 874.4710, Class II, Product Code EOX

Predicate Device

EsoCheck Cell Collection Device (K222366)

Reference Device

EsophaCap@ Swallowable Cellular Retrieval Device (K203450)

Intended Use / Indications for Use

The EsoCheck Cell Collection Device is indicated for use in the collection and retrieval of surface cells of the esophagus in the general population of adults and adolescents, 12 years of age and older.

Device Description

The EsoCheck Cell Collection Device is a non-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.

The subject device is technologically identical to the previously-cleared predicate device (K222366). The only modification to the subject device is of its sterility, which has been modified to non-sterile (i.e., provided non-sterile and not requiring end-user sterilization before use).

Performance Data

All prior testing of the predicate device remains applicable to the subject device because sterilization status could not affect device performance (thus no new performance testing is required), and the prior sterilization method (EtO) constituted worst case test conditions for other types of testing (i.e., biocompatibility and packaging/shelf life).

As additional support that removal of sterilization does not present new safety risks, bioburden testing was performed in accordance with ISO 11737-1 and USP <62>; this testing showed an absence of specific objectionable organisms and acceptable bioburden levels.

Substantial Equivalence

The subject EsoCheck Cell Collection Device is as safe and effective as the predicate EsoCheck Cell Collection Device. The subject device has identical intended uses, indications for use, technology, and principles of operation as the predicate device.

The only difference between the subject device and its predicate device is that the subject device is not provided sterile. Functionally, the ability of cells to adhere to the EsoCheck balloon surface is unimpacted by device sterility. Furthermore, the safety of the nonsterile nature for this device type and its intended use is supported by the FDA clearance of reference device EsophaCap® (K203450). The intended use/indications of use and anatomic location of use for both EsoCheck and EsophaCap are the same, and both devices are provided nonsterile for single use.

Although additional testing was unnecessary to support substantial equivalence (as shown by the reference device), new bioburden testing was performed and showed acceptable levels of bioburden on the non-sterile EsoCheck.

Thus, no new or different questions of safety or effectiveness arise from the subject device's non-sterile nature.

Conclusions

The subject device has identical intended use, indications for use, principles of operation, and technological characteristics as the predicate device. The minor difference in sterility does not raise any new or different questions of safety or effectiveness, as supported by the reference device K203450. Bioburden testing provides further support that the subject EsoCheck is as safe and effective as the predicate EsoCheck device. Thus, the EsoCheck Cell Collection Device is substantially equivalent to its predicate device.