May 3, 2024

Lactation Lab Inc.
Stephanie Canale
CEO
2611 Palm Avenue
Manhattan Beach, California 90266

Re: K234088
Trade/Device Name: Emily's Care Nourish Test System (Model 1)
Regulation Number: 21 CFR 862.1493
Regulation Name: Breast Milk Macronutrients Test System
Regulatory Class: Class II
Product Code: QEI
Dated: April 1, 2024
Received: April 3, 2024

Dear Stephanie Canale:

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 and Part 809); 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
k234088

Device Name
Emily's Care Nourish Test System (Model 1)

Indications for Use *(Describe)*

Emily's Care Nourish Test System (Model 1) quantitatively measures the concentration of protein, fat (triglycerides), and carbohydrates (lactose) in human milk. It also provides calculated values for calories (energy). These measurements, in conjunction with other clinical assessments, may be used to aid in the nutritional management of newborns, including preterm, and infants.

This device is intended for use in healthcare by trained healthcare personnel at point of care or clinical laboratory settings.

The device is for prescription use only.

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 - Emily's Care Nourish Test System (Model 1)

510(k) number: K234088
Date Prepared: May 2, 2024

Submitter:
Lactation Lab Inc.
2611 Palm Avenue
Manhattan Beach, CA 90266

Contact Information:
Stephanie Canale, M.D. CEO and Founder of Lactation Lab Inc.
Phone: 310-508-5265
Email: scanale@lactationlab.com

Device Proprietary Name: Emily's Care Nourish Test System (Model 1)

Regulatory Information:
Regulation section: 21 CFR 862.1493 Breast Milk Macronutrients Test System
Classification: Class II (Special Controls)
Product code(s): QEI
Panel: Clinical Chemistry (75)

Predicate Device:
DEN180007 - Miris Human Milk Analyzer (HMA)

Device Description: The Emily's Care Nourish Test System (Model 1) is an in vitro diagnostic device that consists of the following:

1. iPhone models 12 mini, 12 pro, 12 pro max, 13, 13 pro, 13 pro max, 14 or 14 pro max running iOS 16 or 17
2. Free Emily's Care app to be downloaded on the iPhone app store
3. Single-use test strips, in a desiccant-lined vial
4. Single-use reference card to place the test strip on to be read
5. Pipettes and tubes to collect milk
6. Lightbox

Intended Use:
Emily's Care Nourish Test System (Model 1) quantitatively measures the concentration of protein, fat (triglycerides), carbohydrates (lactose) in human milk. It also provides calculated values for calories (energy). These measurements, in conjunction with other clinical assessments, may be used to aid in the nutritional management of newborns, including preterm, and infants.

This device is intended for use in healthcare by trained healthcare personnel at point of care or clinical laboratory settings.

The device is for prescription use only.

Substantial Equivalence Comparison

Similarities

Item	Candidate Device: k234088 Emily's Care Nourish Test System (Model 1)	Predicate Device: DEN180007 Miris HMA
Intended Use	Quantitative measurement of macronutrients in breast milk.	Same
Intended population	Newborns, including preterm, and infants	Same
Contraindications	Not designed for use with infant formula, other milk feeding products or fortifiers.	Same
Sample Type	Breast milk in liquid form (room temperature)	Same

Differences

Testing Environment	Prescription use in Point Of Care settings	Prescription use in Clinical Laboratories and HMBANA accredited Human Milk Banks
Calibration	Not required by the end user. .	Calibration is performed by the end user prior to analyzing human milk samples.
Measuring Range	Fat: 0.6 - 6.0 g/dl Protein: 0.6 - 2.4 g/dl Carbohydrates/ Lactose 4.5 - 9.5 g/dl	Fat: 0.6 - 6.0 g/dl Crude Protein: 0.8 - 3.0 g/dl True Protein: 0.6 - 2.4 g/dl Carbohydrates: 6.6 - 8.7 g/dl
Principles of Operation	Colorimetric	Mid-infrared (mid-IR) transmission spectroscopy

Bench Testing Summary for Emily's Care Nourish Test System:

The Emily's Care Nourish Test System underwent bench testing to evaluate its performance characteristics, including precision, accuracy (bias), linearity, sensitivity, and interference.

The sponsor also performed flex testing to evaluate the effect of temperature, humidity, and suboptimal handling of the samples or strips. The results showed that the device is adequately robust to conditions that may reasonably be expected in the intended use environment.

Conclusion:

Based on the information provided in this 510(k), the Emily's Care Nourish Test System (Model 1) is substantially equivalent to the predicate and raises no new issues of safety and effectiveness. The testing performed demonstrates that the candidate device is safe and effective for its intended use.