December 21, 2018

Miris AB
% John Smith, Partner
Hogan Lovells US LLP
555 Thirteenth Street
Washington, District of Columbia 20004

Re: DEN180007
Trade/Device Name: Miris Human Milk Analyzer
Regulation Number: 21 CFR 862.1493
Regulation Name: Breast milk macronutrients test system
Regulatory Class: Class II
Product Code: QEI
Dated: October 24, 2018
Received: October 24, 2018

Dear John Smith:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Miris Human Milk Analyzer, a prescription device with the following indications for use:

> The Miris Human Milk Analyzer (HMA) quantitatively measures the concentration of fat, carbohydrate, and protein in human milk. The Miris HMA also provides calculated values for total solids and 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 clinical laboratories.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Miris Human Milk Analyzer, and substantially equivalent devices of this generic type, into Class II under the generic name Breast milk macronutrients test system.

FDA identifies this generic type of device as:

> **Breast Milk Macronutrients Test System**. A breast milk macronutrient test system is a device intended to quantitatively measure fat, protein, and total carbohydrate content in human breast milk. These measurements, in conjunction with other clinical assessments, may be used to aid in the nutritional management of infants.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 24, 2018, FDA received your De Novo requesting classification of the Miris Human Milk Analyzer. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Miris Human Milk Analyzer into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Miris Human Milk Analyzer can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Required Mitigations
Incorrect test results	General controls and special controls (1) and (2)
Incorrect action based on test results	General controls and special control (2)

In combination with the general controls of the FD&C Act, the Breast milk macronutrients test system is subject to the following special controls:

(1) Design verification and validation must include the following:
   (i) An appropriate traceability plan, as determined by FDA, to minimize the risk of drift in the breast milk macronutrient test system results over time.
   (ii) Data that demonstrate appropriate precision, as determined by FDA, of the breast milk macronutrients test system. Precision studies must include assessment of a minimum of three breast milk specimens containing different concentrations (low, medium and high levels) of fat, carbohydrates, and protein. Precision data must include breast milk specimen measurements that are collected at a minimum of three laboratory sites.
   (iii) Data that demonstrate appropriate measurement accuracy, as determined by FDA, of fat, carbohydrates, and protein in breast milk. Measurement accuracy data must include breast milk specimen measurements that are collected at a minimum of one laboratory site.
   (iv) Data from studies appropriate, as determined by FDA, to demonstrate that the device is free from significant interference from substances that could be present in human milk, including hemoglobin, and medications that are used by breastfeeding subjects.

(2) The 21 CFR 809.10 labeling must include the following:
(i) A limiting statement indicating that the results should be used only as an aid in the nutritional management of infants and not as the sole basis for making nutrition decisions.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Breast milk macronutrients test system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Wilmarie Flores at 301-796-2565.

Sincerely,

Courtney H. Lias -S

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