**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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February 3, 2017

BAEBIES, INC.
TAMMY B. CARREA
VICE PRESIDENT, QUALITY ASSURANCE AND REGULATORY AFFAIRS
615 DAVIS DRIVE, SUITE 800, PO BOX 14403
DURHAM, NC 27709

Re: DEN150035
SEEKER System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 862.1488
Regulation Name: Lysosomal storage disorder newborn screening test system
Regulatory Classification: Class II
Product Code: PQW, PQT, PQU, PQV
Dated: July 30, 2015
Received: August 7, 2015

Dear Tammy B. Carrea:

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 SEEKER System, a prescription device with the following indications for use:

> The SEEKER System, including the SEEKER Instrument and the SEEKER LSD Reagent Kit - IDUA|GAA|GBA|GLA for use on the SEEKER Instrument, is intended for quantitative measurement of the activity of α-L-iduronidase, α-D-glucosidase, β-glucocerebrosidase and α-D-galactosidase A from newborn dried blood spot specimens as an aid in screening newborns for Mucopolysaccharidosis Type I, Pompe, Gaucher and Fabry diseases. Reduced activity of these enzymes may be indicative of these lysosomal storage diseases. The enzymes measured using the SEEKER LSD Reagent Kit-IDUA|GAA|GBA|GLA and their associated lysosomal storage diseases are listed below.

| Enzyme (abbreviation) | Disease |
|---|---|
| α-L-iduronidase (IDUA) | Mucopolysaccharidosis Type I (MPS I) |
| α-D-glucosidase (GAA) | Pompe |
| β-glucocerebrosidase (GBA) | Gaucher |
| α-D-galactosidase A (GLA) | Fabry |

FDA concludes that this device should be classified into class II. This order, therefore, classifies the SEEKER System, and substantially equivalent devices of this generic type, into class II under the generic name, "Lysosomal storage disorder newborn screening test system".

FDA identifies this generic type of device as: lysosomal storage disorder newborn screening test system.

A lysosomal storage disorder newborn screening test system is intended to measure lysosomal enzyme levels obtained from dried blood spot specimens on filter paper from newborns as an aid in screening newborns for a lysosomal storage disorder.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

On August 7, 2015, FDA received your *de novo* requesting classification of the SEEKER System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SEEKER System 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 and the recommendations from the August 10, 2016 meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee on the SEEKER System, FDA has determined that the SEEKER System indicated for use as follows:

> The SEEKER System, including the SEEKER Instrument and the SEEKER LSD Reagent Kit - IDUA|GAA|GBA|GLA for use on the SEEKER Instrument, is intended for quantitative measurement of the activity of α-L-iduronidase, α-D-glucosidase, β-glucocerebrosidase and α-D-galactosidase A from newborn dried blood spot specimens as an aid in screening newborns for Mucopolysaccharidosis Type I, Pompe, Gaucher and Fabry diseases. Reduced activity of these enzymes may be indicative of these lysosomal storage diseases. The enzymes measured using the SEEKER LSD Reagent Kit-IDUA|GAA|GBA|GLA and their associated lysosomal storage diseases are listed below.

| Enzyme (abbreviation) | Disorder |
|---|---|
| α-L-iduronidase (IDUA) | Mucopolysaccharidosis Type I (MPS I) |
| α-D-glucosidase (GAA) | Pompe |
| β-glucocerebrosidase (GBA) | Gaucher |
| α-D-galactosidase A (GLA) | Fabry |

can be classified in class II with the establishment of special controls for this type of device. FDA believes that class II special controls identified later in this order, along with the applicable general controls, including the design controls under 21 CFR part 820, 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

| Identified Risks to Health | Required Mitigations |
|---|---|
| Inaccurate test results that provide false negative test results could lead to a newborn to not be detected as a possible lysosomal storage disorder case and to be delayed from timely therapy. | Special Controls (1) and (2) |
| Inaccurate test results that provide false positive test results could lead a newborn to have unnecessary additional confirmatory testing and to add emotional burden to the family of the newborn. | Special Controls (1) and (2) |

In combination with the general controls of the FD&C Act, a lysosomal storage disorder newborn screening test system is subject to the following special controls:

1. Premarket notification submissions must include information that demonstrates the performance characteristics of the device, including:
    - (i) Study results that adequately demonstrate the clinical validity of the device, which shall include information supporting the link between the analyte being measured and the condition being screened. The clinical validity of the device must be demonstrated in a clinical validation study using either well characterized prospectively or retrospectively obtained clinical specimens from the intended use population. Testing in the clinical validation study must be performed by operators representative of the types of operators intended to use the test. The study design of the clinical validation study must assess the effects of sample collection and processing steps on test performance. Confirmed positive specimens must have a diagnosis based on confirmatory diagnostic methods or clinically meaningful information regarding the status of the subject must be obtained.
    - (ii) The reference interval in the normal newborn population for the analyte or analytes measured by the device.
    - (iii) Study results demonstrating the level of carry-over or drift affecting the device performance.
    - (iv) Study results demonstrating the concentrations of the limit of blank, limit of detection, and limit of quantitation of the device. Sample concentrations below the limit of quantitation should not be reported by the device.

(v) Study results, which shall be collected using sample panels from at least three reagent lots and at least three instruments over more than 20 testing days, demonstrating the imprecision of the device. The sample panels must consist of blood spot specimens with a range of analyte concentrations that span the reportable range of the device and must include samples with concentrations in the screen positive range, samples with concentrations at each cutoff, and samples with concentrations in the normal range.

2. Your 21 CFR 809.10 compliant labeling for this device must include:
   (i) A warning that reads "This test is not intended to diagnose lysosomal storage disorders."
   (ii) A warning that reads "Test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation by alternative methods, and clinical evaluation as appropriate."
   (iii) Detailed information on device performance, including the false positive rate and the false negative rate observed in the clinical study.
   (iv) Information on device performance in any relevant subgroup (e.g., age of newborn at time of sample collection, birth weight, sex, gestational age, race, ethnicity) observed in the clinical study.

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Lysosomal storage disorder newborn screening test system they intend to market prior to marketing the device and receive clearance to market from FDA.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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.

If you have any questions concerning this classification order, please contact Paula Caposino at (301) 796-6160.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
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