DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 8, 2016

RebiScan, Inc.
Mr. Justin Shaka
Chief Executive Officer
30 Mount Auburn Street, Suite B
Cambridge, MA 02138

Re: DEN130051
Pediatric Vision Scanner
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 886.1342
Regulation Name: Strabismus Detection Device
Regulatory Classification: Class II
Product Code: PMW
Dated: December 11, 2013
Received: December 13, 2013

Dear Mr. Shaka:

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 Pediatric Vision Scanner, a prescription device under 21 CFR Part 801.109 that is *intended for the automated detection of misalignment of the visual axes using polarized light. It is indicated for the screening of amblyopia and microstrabismus associated with amblyopia in children age 2 to 8 undergoing evaluation in a professional eye care setting and who are responsive to taking direction and who can pay attention for at least 5 seconds.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the Pediatric Vision Scanner, and substantially equivalent devices of this generic type, into class II under the generic name, Strabismus Detection Device.

FDA identifies this generic type of device as:

> **Strabismus Detection Device.** A strabismus detection device is a prescription device designed to simultaneously illuminate both eyes with polarized light for automated detection of strabismus by analyzing foveal birefringence properties.

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 December 13, 2013, FDA received your *de novo* requesting classification of the Pediatric Vision Scanner into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Pediatric Vision Scanner 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 the Pediatric Vision Scanner indicated as follows:

> *"The Pediatric Vision Scanner is intended for the automated detection of misalignment of the visual axes using polarized light. It is indicated for the screening of amblyopia and microstrabismus associated with amblyopia in children age 2 to 8 undergoing evaluation in a professional eye care setting and who are responsive to taking direction and who can pay attention for at least 5 seconds."*

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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Diagnostic Risks (False Positives, False Negatives, No Output)	• Clinical Performance Testing • Non-Clinical Performance Testing • Software Verification, Validation, and Hazard Analysis • Labeling
Electromagnetic Interference with Other Devices	• Electromagnetic Compatibility (EMC) Testing • Labeling
Electrical Shock	• Electrical Safety Testing • Labeling
Ocular Light Toxicity	• Optical Radiation Safety Testing • Software Verification, Validation, and Hazard Analysis • Labeling
Use Error	• Labeling

In combination with the general controls of the FD&C Act, the Strabismus Detection Device is subject to the following special controls:

1. Clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use. Testing must be conducted in a representative patient population and clinical setting for the indicated use. Demonstration of clinical performance must include assessment of sensitivity and specificity compared to a clearly defined reference standard (comprehensive ophthalmological examination comprises age-appropriate visual acuity testing, examination of the external ocular adnexae and orbit, anterior segment evaluation, extraocular motility evaluation, assessment of stereopsis, cycloplegic refraction, and dilated fundus examination).

2. Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use. The following technical characteristics must be evaluated:
    a. Verification of lowest detectable amount of deviation.
    b. Validation of the accuracy and precision at the lowest detectable amount of deviation.

3. Software verification, validation and hazard analysis must be performed.

4. Optical radiation safety testing must demonstrate the device is safe per the directions for use.

5. Performance testing must demonstrate the electromagnetic compatibility of the device.

6. Performance testing must demonstrate the electrical safety of the device.

7. Labeling must include the following:

    a. Summaries of non-clinical and clinical performance testing.
    b. Instructions on how to correctly use and maintain the device.
    c. Instructions and explanation of all user-interface components.
    d. Information related to electromagnetic compatibility and optical radiation classification.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 Strabismus Detection Device 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 Part 801); 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 Elvin Ng at 301-796-6620.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health