U.S. FOOD & DRUG ADMINISTRATION

September 24, 2020

Tangible Science, Inc.
% Bret Andre
Principal Consultant
EyeReg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: DEN200002
Trade/Device Name: Tangible Boost
Regulation Number: 21 CFR 886.5919
Regulation Name: Hydrophilic re-coating solution
Regulatory Class: Class II
Product Code: QMM
Dated: January 10, 2020
Received: January 15, 2020

Dear Bret Andre:

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 Tangible Boost, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Tangible Boost is a monthly treatment to restore the Tangible Hydra-PEG coating and maintain the wettability of Tangible Hydra-PEG treated fluorosilicone acrylate rigid gas permeable lenses. Tangible Boost is intended for prescription (Rx) use only.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Tangible Boost, and substantially equivalent devices of this generic type, into Class II under the generic name Hydrophilic re-coating solution.

FDA identifies this generic type of device as:

> **Hydrophilic re-coating solution**. A hydrophilic re-coating solution is a home use device intended to restore the hydrophilic coating of rigid gas permeable (RGP) contact lenses using reactive coating components.

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 January 13, 2020, FDA received your De Novo requesting classification of the Tangible Boost. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Tangible Boost 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 Tangible Boost 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks	**Mitigation Measures**
Adverse events leading to eye irritation (redness, burning, stinging, discomfort, pain), infection, keratitis, corneal ulcer, loss of visual acuity, or allergic reaction	Clinical performance testing Human factors evaluation Labeling
Adverse tissue reaction	Biocompatibility evaluation Lens solution compatibility testing Coating effectiveness testing Labeling
Infection	Sterility testing and validation Disinfection solution compatibility testing Shelf life testing Labeling
Use error/ improper device use leading to eye irritation (redness, burning, stinging, discomfort, pain), infection, keratitis, corneal ulcer, loss of visual acuity	Clinical performance testing Human factors evaluation Coating performance testing Labeling

In combination with the general controls of the FD&C Act, the hydrophilic re-coating solution is subject to the following special controls:

1. Clinical performance testing must evaluate device safety as assessed by adverse events, slit lamp findings, and maintenance of visual acuity.

2. The patient contacting components of the device and packaging components must be demonstrated to be biocompatible.

3. Performance testing must demonstrate the sterility of the device.

4. Use-related risk analysis must be performed to determine if a self-selection study and human factors validation study must be conducted to demonstrate that users can correctly use the device based solely on reading the directions for use.

5. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

6. Performance testing must demonstrate compatibility with each lens and solution labeled for use with the device.

7. Performance testing must demonstrate the ability of the device to restore the coating of compatible lenses.

8. Labeling must include the following:
    a. Instructions on how to correctly use the device, including instructions to use fresh components for each use;
    b. Descriptions of compatible contact lenses;
    c. Descriptions of compatible care solutions;
    d. A warning that if patients are not sure of their lens material, they should contact their health care provider prior to use; and
    e. A precaution against use with lenses that have not been demonstrated to be compatible with the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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.

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 hydrophilic re-coating solution 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 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 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/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).

If you have any questions concerning the contents of the letter, please contact Elissa Wong at 240-402-0204.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health