# DE NOVO CLASSIFICATION REQUEST FOR TANGIBLE BOOST

## REGULATORY INFORMATION

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.

**NEW REGULATION NUMBER:** 21 CFR 886.5919

**CLASSIFICATION:** Class II

**PRODUCT CODE:** QMM

## BACKGROUND

**DEVICE NAME:** Tangible Boost

**SUBMISSION NUMBER:** DEN200002

**DATE DE NOVO RECEIVED:** January 13, 2020

**CONTACT:** Tangible Science, Inc.
740 Broadway
Redwood City, CA 94063

## 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.

## LIMITATIONS

Use of this device is limited to Hydra-PEG coated fluorosilicone acrylate rigid gas permeable (RGP) contact lenses (CLs).

The sale, distribution, and use of Tangible Boost is restricted to prescription use in accordance with 21 CFR 801.109.

Patient instructions are required for the proper use of the device. Labeling must include instructions on how to correctly use the device.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

The device restores Hydra-PEG coating (which naturally diminishes from the contact lens surface over time) and maintains wettability of Hydra-PEG coated fluorosilicone acrylate RGP CLs.

The device was evaluated in a 3-month clinical performance study in which subjects received new RGP CLs and performed monthly Boost treatment after 1 and 2 months of lens wear. Subjects also disinfected their lenses daily with a compatible multipurpose solution.

Clinical study subjective patient reported outcomes did not demonstrate clinically significant meaningful reduction in contact lens discomfort nor did they demonstrate greater patient preference, as compared to the placebo control group.

## DEVICE DESCRIPTION

Tangible Boost is a monthly treatment specifically for RGP CLs made from fluorosilicone acrylate and manufactured with a Hydra-PEG coating. Tangible Boost is intended for prescription (Rx) use only, and for home use. Tangible Boost is not intended for lens disinfection and must be used in conjunction with a compatible multipurpose solution, as described in the labeling.

Tangible Boost restores the Tangible Hydra-PEG coating and maintains the wettability of Tangible Hydra-PEG treated fluorosilicone acrylate lenses. The device consists of two sterile, preservative-free, unit dose solutions to be combined in the single use, disposable Tangible Boost barrel style lens case (included in the device packaging). Patients who are allergic to any ingredient (e.g. Tangible Hydra-PEG) should not use this device.

As shown in Figure 1 below, to use Tangible Boost, the patient combines two tubes containing the Boost solutions into the Boost case. The patient rubs their lenses with compatible multipurpose solution for 20 seconds. Multipurpose solutions that are compatible with this device are Menicon Unique pH® and Boston SIMPLUS® Multi-Action Solution. Then, the patient places their lenses into the Boost case lens compartments and soaks the lenses in the combined Boost solution for 30 minutes.

After soaking, patients dispose of the used solution in the Boost case. Patients then rinse their lenses with the compatible multipurpose solution, by submerging the lenses for 20 seconds. The patient then removes the lenses from the Boost case and discards the case. After rinsing, the patient disinfects their lenses in a compatible multipurpose solution overnight, using a standard lens case. Only after this overnight disinfection step are the lenses ready to be worn.

Please refer to the labeling documents for a complete list of warnings, precautions and contraindications.

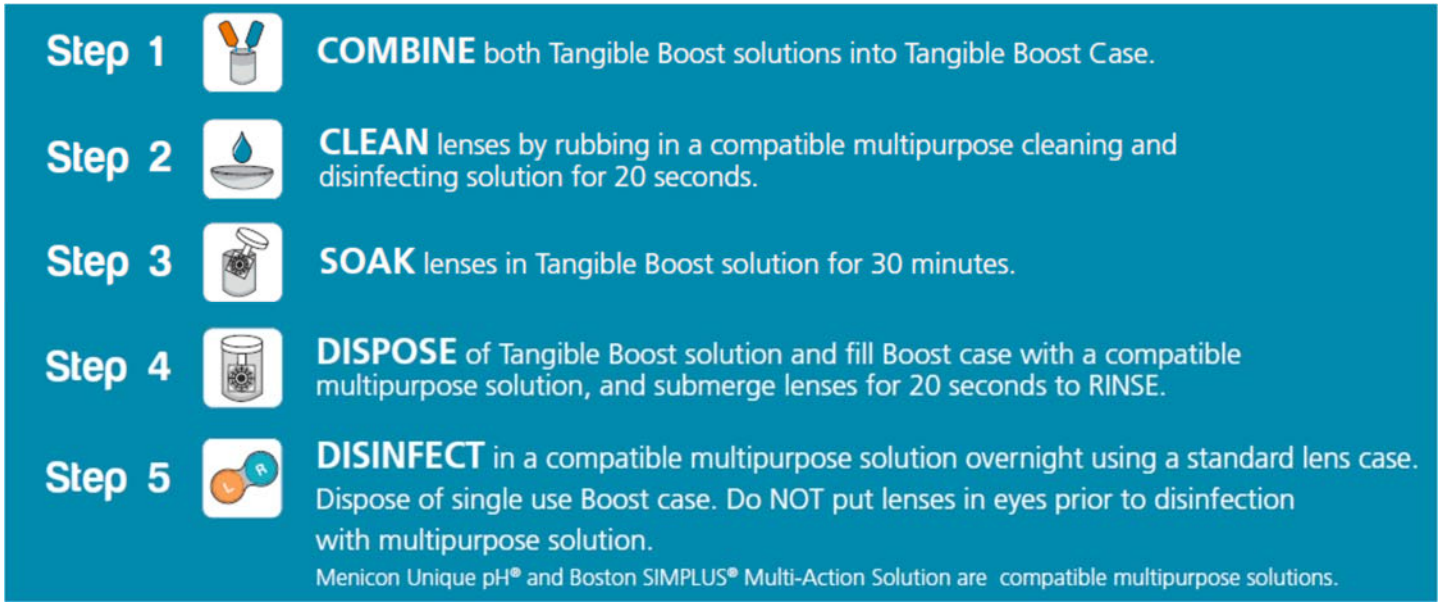


**Figure 1. Tangible Boost**

Figure 1 shows Tangible Boost instructions for use. These instructions are excerpted from the device labeling.

## SUMMARY OF NONCLINICAL/BENCH STUDIES

### BIOCOMPATIBILITY/MATERIALS

The Tangible Boost solutions were assessed (Table 1) for cytotoxicity, sensitization, ocular irritation, acute oral toxicity, and ocular biocompatibility endpoints. The biocompatibility testing was performed in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", International Standard Organization (ISO) 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, - Part 5: Tests for in vitro cytotoxicity, - Part 10: Tests for irritation and skin sensitization, and - Part 11: Tests for systemic toxicity, and ISO 9394- Ophthalmic optics — Contact lenses and contact lens care products—Determination of biocompatibility by ocular study with rabbit eyes. Results demonstrated acceptable performance.

**Table 1. Biocompatibility Testing on Tangible Boost Solutions**

| Test | Purpose | Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Cytotoxicity | Evaluate the potential for cellular toxicity of the device. | MEM Elution w/ L-929 Mouse Fibroblast Cells (ISO 10993-5) | Non-cytotoxic | Pass |

| Test | Purpose | Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Sensitization | Evaluate the sensitization capacity of the device. | (b) (4) Maximization (ISO 10993-10) | Non-sensitizer | Pass |
| Ocular irritation | Evaluate the potential of the device to induce ocular irritation. | Ocular irritation (ISO 10993-10) | Non-irritant | Pass |
| Acute Oral Toxicity | Evaluate the potential for oral systemic toxicity. | Acute Oral Toxicity (ISO 10993-11) | Non-toxic | Pass |
| Ocular Biocompatibility | Evaluate the ocular biocompatibility. | Ocular toxicity (ISO 9394) | Non-toxic | Pass |

All biocompatibility testing was conducted in accordance with the provisions of 21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

The Tangible Boost packaging was assessed (Table 2) for cytotoxicity, ocular irritation and acute systemic toxicity testing. The biocompatibility testing was performed in accordance with International Standard Organization (ISO) 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, - Part 5: Tests for in vitro cytotoxicity, - Part 10: Tests for irritation and skin sensitization, and - Part 11: Tests for systemic toxicity. Results demonstrated acceptable performance.

**Table 2. Biocompatibility Testing on Tangible Boost Packaging**

| Test | Purpose | Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Cytotoxicity: Packaging | Evaluate the potential for cellular toxicity of the Tangible Boost packaging. | MEM Elution w/ L-929 Mouse Fibroblast Cells (ISO 10993-5) | Non-cytotoxic | Pass |
| Ocular irritation: Packaging | Evaluate the potential of the Tangible Boost packaging to induce ocular irritation. | Ocular irritation (ISO 10993-10) | Non-irritant | Pass |
| Acute Systemic Toxicity : Packaging | Evaluate the potential for ocular systemic toxicity of the Tangible Boost packaging. | Acute Ocular Toxicity (ISO 10993-11) | Non-toxic | Pass |

All biocompatibility testing was conducted in accordance with the provisions of 21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

Biocompatibility testing demonstrated that the Tangible Boost solutions and packaging do not illicit a toxicological response. It is important to note that the Boost Case was previously cleared under K991206.

## SHELF LIFE/STERILITY

Tangible Boost is sterilized by filtration and is then aseptically filled into single-use vials. The sterilizing filtration process was validated following recommendations in ANSI/AAMI/ISO 13408-2 Aseptic Processing of Health Care Products – Part 2: Sterilizing Filtration. Steam is used for sterilization in place (SIP) of the sterile circuit and the success of the SIP cycles is confirmed with biological indicators. Environmental monitoring and the aseptic filling process were validated following recommendations in the FDA guidance document Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice. Disinfection efficacy testing was performed following recommendations in ISO14729:2001 Ophthalmic Optics — Contact Lens Care Products — Microbiological Requirements and Test Methods for Products and Regimens for Hygienic Management of Contact Lenses to demonstrate that Tangible Boost does not hinder the ability of daily cleaning solutions to disinfect. Tangible Boost was demonstrated to be bacteriostatic and fungistatic within the 30-minute treatment time frame following recommendations in the FDA guidance document Guidance for Industry – Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products. Sterility testing will be performed for lot release for each batch of Tangible Boost in accordance with USP <71>.

Shelf life of the sterile barrier packaging was established for 2 years under accelerated aging conditions and 12 months under real time conditions following recommendations in the FDA guidance document Guidance for Industry – Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products using the vacuum decay container closure integrity test (ASTM F2338 Standard Test Methods for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method). Transit testing was performed to evaluate the ability of Tangible Boost to withstand possible stressors during shipment following recommendations in ASTM D4332 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing and ASTM 4169 Standard Practice for Performance Testing of Shipping Containers and Systems. The transit events simulated in the testing included manual handling, stacking (compression), loose load, low pressure, vehicle vibration, and concentrated impact, as recommended by ASTM D4169.

## PERFORMANCE TESTING - BENCH

The following chemistry/materials testing was performed for the Tangible Boost Solution on representative fluorosilicone acrylate rigid gas permeable (RGP) contact lenses :

- Lens/solution compatibility testing per ISO 11981:2009 was performed to demonstrate the compatibility of representative RGP contact lenses and associated care products (compatible care products are specified in the labeling)

- Contact angle/wettability testing to demonstrate the ability of the device to maintain the wettability of compatible RGP lenses. See Figure 2.
- Thin film Ellipsometry/coating thickness testing to demonstrate the ability of the device to restore the Hydra-PEG coating on compatible RGP lenses. See Figure 3.

- Shelf-life stability testing to evaluate the functional performance (wettability and coating thickness) and solution parameters of the boost solution though the duration of the proposed shelf-life

(b) (4)

**Figure 2. Contact Angle Measurement**

Contact angle of Tangible Hydra-PEG (HPT) coated fluorosilicone acrylate contact lenses was measured over 12 months with or without monthly Tangible Boost treatment. The darker point/lines are advancing contact angles and lighter points/lines are the receding angles. The data indicates that as compared to untreated control, Tangible Boost treatment reduces the contact angle of the lenses.


**Figure 3. Ellipsometry/Coating Thickness**

Delta values were measured by an ellipsometer. The difference in delta values between the coated and uncoated surface (Delta Delta) is proportional to the coating thickness. The thickness of the coating over time was measured across multiple cycles of simulated wear and Tangible Boost treatments or control (no Tangible Boost treatment). This data demonstrates that Tangible Boost treatment increased coating thickness to close its original value and that Tangible Boost treatment continued be effective over 12 monthly treatments.

## HUMAN FACTORS/USABILITY TESTING

To assess the ability of a patient to properly use the two-component Tangible Boost system, a human factors/usability (HF/U) study was performed according to the Human Factors guidance document, Applying Human Factors and Usability Engineering to Medical Devices. Testing was conducted with 15 laypersons from male and female users from all age groups to assess all tasks and to monitor for unforeseen use errors that could lead to serious harm.

The results of the HF/U study did not identify any unforeseen use errors or unacceptable residual risks. The reference material assessment of the HF/U study confirmed that all participants understood that they needed to disinfect the lenses after Boost treatment, and that they should not place the Boost solution directly in their eyes. All participants also demonstrated that they knew the treatment is intended to be monthly, as listed on the outer box.

The human factors/usability testing results demonstrated that the test participants understand the key information such as usage frequency, disinfection requirement, no direct eye contact with solution.

## SUMMARY OF CLINICAL INFORMATION

A clinical study was conducted to evaluate safety and effectiveness of Tangible Boost to replenish Hydra-PEG coating on RGP contact lenses. It was a 3-month, subject and investigator masked, randomized, placebo-controlled study. Subjects were fitted with Hydra-PEG treated fluorosilicone acrylate RGPs (corneal or scleral). After 1 and 2 months of lens wear, subjects treated their lenses with Tangible Boost or saline placebo. Care regime utilized Unique pH multipurpose solution (dispensed for the duration of the trial) and subjects wearing scleral lenses also received Purilens saline as a filling solution. Sample size was 30 subjects; 20 test and 10 control.

Primary safety endpoints included assessment of Adverse Events and slit lamp findings including corneal staining, as well as contact lens discontinuations. Primary effectiveness endpoints included assessment of lens performance as evidenced by no reduction VA and RGP lens fit. Secondary efficacy endpoints included non-invasive tear break-up time (TBUT) and several patient-reported assessments of subjective symptoms and preference.

**Table 3. Clinical Study Schedule Summary and Inclusion/Exclusion Criteria**

| | |
|---|---|
| Study Visits | There was a minimum of five study visits:<br>1. Baseline<br>2. Lens dispensing visit<br>3. Tangible Boost dispensing visit<br>4. 1-day follow-up<br>5. 60-day follow-up |
| Inclusion criteria | • Willing and able to sign the informed Consent form<br>• Written documentation has been obtained in accordance with the relevant country and local privacy requirements, where applicable<br>• Male or female<br>• 18 years of age and older prior to the initial visit<br>• Established scleral or corneal rigid contact lens wearer<br>• In the opinion of the investigator, the subject has the ability to follow study instructions<br>• In the opinion of the investigator, the subject has the ability to complete all study procedures and visits |
| Exclusion criteria | • Has never worn either scleral or corneal contact lenses before<br>• Does not possess a usable pair of spectacles<br>• Has any ocular disease or abnormality that would affect the wearing of contact lenses<br>• Is aphakic (i.e., missing their natural lens inside the eye) |

| | |
|---|---|
| | • Is currently participating in any other type of eye-related clinical or research study<br>• Is pregnant or nursing as reported by the subject<br>• Has a condition or is in a situation which, in the investigator's opinion, may put the subject at significant risk, may confound study outcomes, or may significantly interfere with the subject's participation in the study<br>• Has a known and self-reported allergy to components in the device<br>• Has had previous ocular surgery within the past 12 weeks<br>• Is unable to consent<br>• Is a prisoner |

**Primary Efficacy Endpoints**:

- **Visual Acuity (VA)**: No decline in VA throughout the study, endpoint was met. No statistically significant change in VA for test and control group observed during pre-treatment, 1 day post-treatment and final visit follow-up.

(b) (4)

**Figure 4. Visual Acuity**

Visual acuity was measured on a logMAR scale prior to treatment, 1 day after treatment, and at the final follow-up visit.

**Lens Fit:** No decline in Lens Fit throughout the study, endpoint was met. Changes in lens fit were not observed at higher rate for Boost group compared to placebo (amount consistent with changes expected day-to-day or based on number of hours of wear prior to measurement).

**Table 4. Movement**

| | Boost | | Placebo | |
|---|---|---|---|---|
| | Scleral | Corneal | Scleral | Corneal |
| No change | (b) (4) | | | |
| Movement improved | | | | |
| Increased movement causing destabilization | | | | |
| Loss of movement leading to poor fit | | | | |
| Other | | | | |

**Table 5. Centration**

| | Boost | | Placebo | |
|---|---|---|---|---|
| | Scleral | Corneal | Scleral | Corneal |
| No change | (b) (4) | | | |
| Centration improved | | | | |
| Change of centration, still adequate | | | | |
| Decentered inadequately | | | | |
| Other | | | | |
| Total | | | | |

**Table 6. Apical Clearance**

| | Boost | | Placebo | |
|---|---|---|---|---|
| | Scleral | Corneal | Scleral | Corneal |
| No change | (b) (4) | | | |
| Clearance increased, still adequate | | | | |
| Clearance decreased, still adequate | | | | |
| Inadequately low clearance | | | | |
| Excess clearance | | | | |
| Total | | | | |

**Table 7. Limbal Clearance**

| | Boost | | Placebo | |
|---|---|---|---|---|
| | Scleral | Corneal | Scleral | Corneal |

| | |
|---|---|
| No change | (b) (4) |
| Clearance increased, still acceptable | |
| Clearance decreased, still adequate | |
| Inadequate clearance | |
| Excess clearance | |
| Total | |

**Table 8. Landing Zone**

| | Boost | | Placebo | |
|---|---|---|---|---|
| | Scleral | Corneal | Scleral | Corneal |
| No change | (b) (4) | | | |
| Developing of blanching | | | | |
| Development of bearing | | | | |
| Improvement of blanching/bearing | | | | |
| Improvement in lens edge lift | | | | |
| Development of lens edge lift | | | | |
| Inadequate edge fit | | | | |
| Total | | | | |

**Secondary Effectiveness Endpoints**:

- **Tear Film Break-Up Time (TBUT)**: maintained baseline TBUT (no worsening) for both Boost and Placebo subject groups at the timepoints shown in the graphbelow.

(b) (4)

**Figure 5. Tear Film Break-Up Time (TBUT)**

Non-invasive keratography tear break-up time was used to evaluate the average tear film break-up time. Measurements were taken at V3 (prior to treatment, after 1 month in Hydra-PEG lenses), V4, (1 day after first Boost treatment), and V5 (final follow-up).

- **Subjective Symptoms**:
    - **Contact Lens Dry Eye Questionnaire (CLDEQ)**: Patient-reported changes in symptoms assessed by the CLDEQ questionnaire were not clinically significant over the course of study.


**Figure 6. Contact Lens Dry Eye Questionnaire (CLDEQ)**
CLDEQ survey results at the pre-treatment visit 3 (baseline in Hydra-PEG lenses), 1 day after first Boost treatment (visit 4), and final follow-up (visit 5).

- **Visual analog scales (VAS)** for lens comfort score: Patient-reported changes in comfort were not clinically significant nor statistically significant over the timepoints shown in the plots below.


**Figure 7. Visual analog scales (VAS)**
VAS scores at the pre-treatment visit (visit 3), 1 day after first Boost treatment (visit 4), and final follow-up (visit 5).

- **Preference:** Subjects were asked whether they preferred lenses before Boost treatment, after treatment, or no preference. Patient-reported changes in comfort were not clinically significant over the course of study. Additionally, the noted differences were not statistically significant.

**Table 9.** Boost preference at visit 4 (1 day after first Boost treatment) and visit 5 (final follow-up)

| | Visit 4 | | Visit 5 | |
|---|---|---|---|---|
| | Boost | Placebo | Boost | Placebo |
| pre-Boost | (b) (4) | | | |
| post-Boost | | | | |
| No preference | | | | |

**Safety Endpoints**:

- **Adverse Events (AEs):** There were no reported serious adverse events (SAEs), and similar overall AE incidence (19% Boost group, 20% control group).
    - **1 AE possibly related to Boost - mild allergic-type response to CLs after Boost treatment,** reaction similar to the patient's initial response to Hydra-PEG coated lenses indicating possible allergy or sensitivity to Hydra-PEG coating. Patients with Hydra-PEG allergy would be expected to discontinue wearing Hydra-PEG CLs, making them ineligible for Boost Rx. Patients with allergy or sensitivity to Tangible Hydra-PEG shouldn't use Boost.
    - **1 AE possibly related to Tangible Boost but unlikely - keratitis**, was asymptomatic and resolved by next visit without treatment (this type of reaction noted to be relatively common with scleral lenses due to trapping of tear solution under lens bowl), patient went on to use Boost a second time without adverse outcome.

**Table 10. Summary of Adverse Events**

| Subject | Treatment Arm | Description | Related to Tangible Boost treatment? |
|---|---|---|---|
| 01 | Unassigned | Developed corneal hydrops (common with advanced keratoconus) prior to lens dispense or assignment to treatment group. | No |
| 12 | Boost | Developed upper respiratory infection, no ocular symptoms. Prescribed Keflex by outside doctor. | No |
| 05 | Boost | Mild allergic-type response (grittiness, redness, discomfort) to lenses after Boost treatment. Used Progent to strip Hydra-PEG coating, discontinued use of Boost, and used artificial tears for 1-2 days. No additional treatment was necessary. Patient reported that these symptoms were also present upon initial receipt of the Hydra-PEG lenses, but that symptoms resolved after ~1.5 weeks. | Possibly, but symptoms were present prior to Boost treatment. |
| 19 | Placebo | Mild swelling and hyperemia of inferior nasal conjunctiva. Instructed to discontinue lens wear for 3-4 days. | No |
| 09 | Placebo | Subject reported for visit with red sore left eye. Reported getting little sleep the past few days and stated that this has occurred in the past. Subject used artificial tears to relieve symptoms. | No |
| 32 | Boost | Developed contact lens-associated acute red eye (CLARE) after lens dispense, which was resolved prior to being seen by study investigator 2 days after event. Exhibited preservative toxicity-type corneal sensitivity reaction. Subject was educated about rinsing the lens bowl prior to insertion and issue resolved. Occurred prior to Boost dispense. | No |
| 25 | Boost | Developed asymptomatic keratitis which resolved without treatment. Subject was monitored, and condition was resolved by the next study visit. | Possibly related |

- **Corneal Staining:** No increase in corneal staining for Boost group compared to placebo group


**Figure 8. Corneal Staining**
Corneal staining scores at pretreatment visit (visit 3), 1 day after first Boost treatment (visit 4), and final follow-up (visit 5). Corneal staining was evaluated on a scale of (b) (4) in each of 5 regions. This graph shows the total of the scores from the 5 regions.

- **Discontinuations**: No subjects were discontinued from the study.

Pediatric Extrapolation
In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

## LABELING
The device labeling is adequate and meets the requirements of 21 CFR 801.109.

Package insert includes device description, Indications for Use with requirement for prescription use only, contraindications, warnings, precautions, potential adverse reactions, and instructions for use including compatible multipurpose solutions for post-Boost and daily disinfection of lenses.

## RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a hydrophilic re-coating solution and the measures necessary to mitigate these risks.

Table 11 – 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<br>Human factors evaluation<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation |

| | |
|---|---|
| | Lens solution compatibility testing<br>Coating effectiveness testing<br>Labeling |
| Infection | Sterility testing and validation<br>Disinfection solution compatibility testing<br>Shelf life testing<br>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<br>Human factors evaluation<br>Coating performance testing<br>Labeling |

**SPECIAL CONTROLS**

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.

## BENEFIT-RISK DETERMINATION

The risks and benefits of the Tangible Boost device are based on non-clinical performance data as well data collected in a clinical study. The device demonstrated an acceptable safety profile in the clinical study, with no SAEs and similar overall AE incidence (2 possibly device-related, a mild allergic-type reaction to Hydra-PEG and a transient asymptomatic keratitis consistent with scleral lens wear), no increase in corneal staining, and no lens discontinuations. Risks associated with use of the Boost device (or mis-use) include adverse reactions leading to eye irritation (redness, burning, stinging, discomfort, pain), infection, keratitis, corneal ulcer, loss of visual acuity, or allergic reaction.

The probable benefits of the device are based on non-clinical laboratory and bench data, as well as data collected in a clinical study. Boost treatment restores Hydra-PEG coating and maintains contact lens wettability as demonstrated by wetting angle data (bench testing). In the clinical study, compared to a placebo control group, the device did not result in reduction of visual acuity, change in lens fit, or worsening of tear break-up time. Clinical study subjective patient-reported outcomes did not demonstrate clinically significant meaningful reduction in contact lens discomfort nor did they demonstrate greater patient preference, as compared to the placebo control group.

### Patient Perspectives

Patient preference information was provided as described in Table 9 above. The information indicated no clinically meaningful or statistically significant difference in preference in terms of lens comfort with use of Tangible Boost solution.

### Benefit/Risk Conclusion

In conclusion, given the available information above, the probable benefits outweigh the probable risks for Tangible Boost. The device provides probable benefits, and the probable risks can be mitigated by use of general controls and the identified special controls.

## CONCLUSION

The De Novo request for Tangible Boost is granted and the device is classified as follows:

Product Code: QMM
Device Type: Hydrophilic re-coating solution
Class: II
Regulation Number: 21 CFR 886.5919