# 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**The assigned 510(k) number is: K181566**

## I. SUBMITTER

Date Prepared: Sept 18th 2018

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## II. DEVICE

Trade Name: **Nutrifill**

Common Name: Contact Lens Insertion Solution

Classification Name: Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)

Regulatory Class: Class II

Product Code: MRC

## III. PREDICATE DEVICE

The Nutrifill preservative free insertion solution is substantially equivalent in terms of actions and indications to the following predicate device(s):

- "LensGiene™ Sterile Saline Solution (Alternate Trade Name: ScleralFil)"
  By Bausch + Lomb, Inc.
  510(k) number: K161622
  Device Classification: II

- "Menicon Saline Rinse Solution"
  By Menicon Co., Ltd.
  510(k) number: K151768
  Device Classification: II

## IV. DEVICE DESCRIPTION

The Nutrifill preservative free insertion solution is a sterile isotonic buffered solution containing electrolytes (calcium, magnesium, potassium, phosphate, sodium) in a single dose, carry-on size 10ml vial. It rinses loose debris and cleaning solution off rigid gas permeable (RGP), hard and hybrid contact lenses prior to insertion. The sterile solution can be used to rinse contact lens cases and contact lenses as needed throughout the day.

## V. INDICATIONS FOR USE

The Nutrifill preservative free insertion solution is indicated as an insertion solution for large diameter (scleral), hybrid and rigid gas permeable (RGP) contact lenses following proper lens care disinfection as recommended by the eye care practitioner. This solution may also be used for rinsing debris and lens cleaners from rigid gas permeable, hybrid and hard contact lenses, as a rinse for contact lens cases and may be used as needed throughout the day to rinse contact lenses.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The Nutrifill preservative free insertion solution is substantially equivalent to the predicate devices in terms of the following:

- Intended use
- Indications for use
- Actions
- Classification – Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)
- How supplied (sterile, single dose)
- Preservative free formulation

The Nutrifill preservative free insertion solution is unique from the predicate device in terms of the

following:

- Nutrifill contains additional electrolytes (calcium, magnesium, potassium, phosphate)
- Nutrifill is buffered with a phosphate buffer at normal ocular pH and osmolarity

The following matrix illustrates the intended use and other characteristics of the Nutrifill preservative free insertion solution, as well as the predicate device.

| | **Contamac, Ltd. Nutrifill** | **Bausch + Lomb, Inc. LensGiene™ Sterile Saline Solution (ScleralFil)** | **Menicon Co., Ltd. Menicon Saline Rinse Solution** |
|---|---|---|---|
| | New Device | Predicate Device (K161622) | Predicate Device (K151768) |
| **Intended Use** | The Nutrifill preservative free insertion solution is indicated as an insertion solution for large diameter (scleral) and hybrid contact lenses following proper lens care disinfection as recommended by the eye care practitioner. This solution may also be used for rinsing debris and lens cleaners from rigid gas permeable, hybrid and hard contact lenses, as a rinse for contact lens cases and may be used as needed throughout the day to rinse contact lenses. | The LensGiene™ Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The LensGiene™ Sterile Saline Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses. | For use following proper lens disinfection as recommended by the eye care practitioner. The Menicon Saline Rinse Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses. |
| **Classification** | 21 CFR 886.5918 | 21 CFR 886.5918 ; 21 CFR 886.5928 | 21 CFR 886.5918 ; 21 CFR 886.5928 |
| **Product Code** | MRC | MRC; LPN | MRC; LPN |
| **Class** | Class II | Class II | Class II |
| **Volume** | 10 mL per dose | 10 mL per dose | 5 mL per dose |
| **Preservative Free** | Yes | Yes | Yes |
| **Single or Multi Dose** | Single Dose | Single Dose | Single Dose |
| **Sterility** | Sterile | Sterile | Sterile |
| **Container** | Plastic resin container with twist off cap | Plastic resin container with twist off cap | Plastic resin container with twist off cap |
| **Contains Electrolytes (Calcium, Magnesium, Potassium, Phosphate)** | Yes | No | No |

## VII. PERFORMANCE DATA

*~ Non-Clinical Studies ~*

A series of studies were completed to demonstrate the substantial equivalence of the Nutrifill preservative free insertion solution to the predicate device. Results of non-clinical testing demonstrate:

- The Nutrifill solution is non-toxic and non-irritating
- The final packaging is non-toxic and non-irritating

*~ Clinical Studies ~*

Clinical studies involving the Nutrifill solution were unnecessary for this application. Lens care solutions used with this Nutrifill solution are already cleared for use as cleaning, rinsing, disinfection and storage solutions for contact lenses.

## VIII. CONCLUSIONS

Substantial Equivalence

Based on the composition of the solution and results of non-clinical testing presented in this Premarket Notification, the Nutrifill preservative free insertion solution is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.