SAUFLON MULTIPURPOSE SOLUTION 510(k)
Date of Revision 15th May 2013

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510(k) SUMMARY

SAUFLON MULTIPURPOSE SOLUTION

Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, disinfection, removal of proteins, storage and conditioning of soft (hydrophilic) contact lenses including silicone hydrogel lenses, as recommended by the eye care practitioner. The Sauflon Multipurpose Solution is identical to that cleared in K974485 and K030278. The purpose of this submission is to add the indication for use with Silicone Hydrogel Lenses.

1. Submitted by:

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UK

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2. Device name

Common Name: Multipurpose Solution

Proprietary Name: Sauflon Multipurpose Solution

3. Classification:

Class II
(Performance Standards)
21 CFR 886.5928
Soft (hydrophilic) contact lens solution

4. Substantial Equivalence:

The product is substantial equivalent to the currently marketed Aquify Multipurpose Disinfecting Solution (K050250/K033608)

5. Device Description:

Sauflon Multipurpose Solution is a sterile, isotonic solution that contains poloxamer, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. Contains no chlorohexidine or thimerosal.

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6. Indications for use: Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, disinfection, removal of proteins, storage and conditioning of soft (hydrophilic) contact lenses including silicone hydrogel lenses, as recommended by the eye care practitioner

7. Pre-clinical Testing

Silicone Hydrogel lens compatibility
A series of compatibility studies were conducted assessing the Sauflon Multipurpose Solution with currently marketed Silicone Hydrogel lenses. The results of these studies confirm that the Sauflon Multipurpose Solution is compatible with Silicone Hydrogel lenses.

Toxicology
Sauflon Multipurpose Solution was shown to be non-toxic in all cytotoxicity, systemic toxicity and ocular irritation testing.

Microbiology
A series of microbiological studies were conducted to demonstrate the disinfection efficacy, preservative efficacy and thus safety of the Sauflon Multipurpose Solution. The Sauflon Multipurpose Solution met the requirements of this testing.

8. Clinical Studies

A clinical trial of circa 250 subjects, using the Sauflon Multipurpose Solution with **four different silicone hydrogel contact lens** brands and one conventional hydrogel control lens was conducted over a period of two months, with a control group using Ciba Vision Aquify Multi- Purpose Solution. The results of this study showed the safety, acceptability and substantial equivalence of the Sauflon Multipurpose Solution to the predicate device for its intended use.

9. Technological Characteristics

The sponsor considers Sauflon Multipurpose Solution to be substantially equivalent to the current marketed product Aquify Multi- Purpose Solution. The following table shows a comparison of the Sauflon Multipurpose Solution to the predicate device, Aquify.

Sauflon Multipurpose solution is also identical to the currently marketed Sauflon Multipurpose solution which has already been previously reviewed by the FDA under 510(k)'s K974485 and K030278. The purpose of this submission is to add the indication for use with Silicone Hydrogel Lenses.

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Indications for use	**SAUFLON MULTIPURPOSE SOLUTION**	AQUIFY MULTI-PURPOSE SOLUTION
	Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins, storage and conditioning of soft (hydrophilic) contact lenses (including Silicone Hydrogel Lenses) replaced in 30 days or less, as recommended by the eye care practitioner.	Aquify Multi-Purpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins, storage and conditioning of soft (hydrophilic) contact lenses (including Silicone Hydrogel Lenses) replaced in 30 days or less, as recommended by the eye care practitioner.
Product description		
	Sauflon Multipurpose Solution is a sterile, isotonic solution that contains poloxamer 188, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. Contains no chlorohexidine or thimerosal.	Aquify Multi-Purpose Solution is a sterile, aqueous solution that contains sorbitol, tromethamine, pluronic F127, sodium phosphate dihydrogen, Dexpant 5 (dexpanthenol) and edetate disodium dihydrate; preserved with polyhexanide 0.0001%. Contains no chlorohexidine or thimerosal.
Product Characteristics		
Active ingredient/preservative	Polyhexamethylene biguanide	Polyhexamethylene biguanide
Chelating agent	Disodium edetate	edetate disodium dihydrate
Tonicity agent	Sodium Chloride	Sorbitol
Surfactant cleaner	Poloxamer 188	Pluronic F127
Lubricant	N/A	N/A
Sterility	Sterile	Sterile
Performance		
Compatibility	Compatible with soft (hydrophilic) contact lenses, groups 1 and 4 as per 510(k) K974485/ K030278 and with 4 representative marketed silicone hydrogel lenses.	Compatible with soft (hydrophilic) contact lenses and silicone hydrogel lenses.
Clinical	Substantially equivalent to Aquify	
Toxicology	Non-toxic in all cytotoxicity and ocular irritation tests.	

10. Conclusions

The data provided in this 510k submission concludes that Sauflon Multipurpose Solution for use in soft contact lenses including silicone hydrogel lenses is substantially equivalent to the Aquify Multi-Purpose Disinfecting Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Sauflon Pharmaceuticals Ltd
% Dr. Christopher Smejkal
Strategic Technical Projects Manager
49-53 York Street
Twickenham, Middlesex TW1 3LP England

Re: K130734
Trade/Device Name: Sauflon Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: March 25, 2013
Received: March 29, 2013

Dear Dr. Smejkal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K130734

SAUFLON MULTIPURPOSE SOLUTION 510(k)

INDICATIONS FOR USE

510(k) Number (if known): K130734

Device Name: Sauflon Multipurpose Solution

Indications For Use: Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, disinfection, removal of proteins, storage and conditioning of soft (hydrophilic) contact lenses including silicone hydrogel lenses, as recommended by the eye care practitioner

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	√

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

J Angelo Green -S
2013.05.14 16:06:18 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K130734