7.0

510(k) SUMMARY

SAUFLON MULTIPURPOSE SOLUTION

1.	**Submitted by:**	**Sauflon Pharmaceuticals Ltd** 49-53 York Street Twickenham TW1 3LP UK
	Official correspondent:	Ligia Delacruz, PhD Regulatory Affairs Manager
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 substantially equivalent to the currently marketed Complete Brand Multi-Purpose Solution – No Rub
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. Sauflon Multipurpose Solution remains unchanged from the previously approved product in K974485, except for the revised directions for use.
6.	**Intended use:**	The Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins and storage and soft (hydrophilic) contact lenses, as recommended by the eye care practitioner

7. Pre-clinical Testing

Solution compatibility
Details of the compatibility study on the Sauflon Multipurpose Solution are contained in K974485

Toxicology
The toxicological testing of Sauflon Multipurpose Solution is contained in K974485

SAUFLON MULTIPURPOSE SOLUTION CONTAINER
The Sauflon Multipurpose solution container components meet the requirements of the USP<661> for containers and closures for ophthalmic preparations, and it has been confirmed by the appropriate tests (i.e the cytotoxicity, ocular irritancy, and systemic toxicity tests).

Microbiology

Sterility
The Sauflon Multipurpose Solution meets the requirements of sterility testing as per K974485.

Preservative efficacy
The Sauflon Multipurpose Solution meets the requirements of the preservative efficacy test with rechallenge at 14 days as per K974485.

Disinfection Efficacy
The Sauflon Multipurpose Solution meets the requirements of both the stand-alone with organic load disinfection test and the regimen test.

8. Clinical Studies

A clinical trial of 3 months usage of the Sauflon Multipurpose Solution by 50 subjects, wearing soft (hydrophilic) contact lenses of either group II and IV, compared to 21 control subjects using to the AMO Complete Brand Multi-Purpose Solution – No Rub, showed the safety, acceptability and substantial equivalence of the Sauflon Multipurpose Solution to the predicate device for its intended use.

9. Conclusions
The Sauflon Multipurpose Solution for use in a no rub regimen for lenses replaced in 30 days or less is substantially equivalent to the AMO Complete Brand Multi-Purpose Solution – No Rub.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2003

Sauflon Pharmaceuticals Ltd.
c/o Dr. Ligia Delacruz
Regulatory Affairs Manager
49-53 York St.
Twickenham, Middlesex
TW1 3LP
United Kingdom

Re: K030278
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: June 11, 2003
Received: June 13, 2003

Dear Dr. Ligia Delacruz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Sauflon Multipurpose Solution

Indications For Use: The Sauflon Multipurpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins and storage of soft (hydrophilic) contact lenses, as recommended by the eye care practitioner

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030278

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

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

Prescription Use _____ OR Over-The Counter X
(Per 21 CFR 801.109)