MAY 15 2006

K052832

510(K) SUMMARY AS REQUIRED BY SECTION 807.92(c)

SUBMITTER INFORMATION:

Company Name:	Sauflon Pharmaceuticals Ltd.
Address:	49 – 53 York Street Twickenham Middlesex TW1 3LP
Phone:	020 8322 4231
Fax:	020 8891 2833
Contact Person:	Ms Tanya Fair

DATE SUMMARY PREPARED: 22nd September 2005

DATE SUMMARY REVISED: 11th May 2006

DEVICE NAME:

Trade Name:	SAUFLON New Day (methafilcon A) Soft (Hydrophilic) Visibility Tinted Daily Disposable Contact Lens
Common Name:	Contact Lens
Classification:	CLASS II (21 CFR 886.5925) CODE – MVN;LPL SOFT (HYDROPHILIC) CONTACT LENS

SUBSTANTIAL EQUIVALENCE:

SAUFLON New Day® (methafilcon A) Soft (hydrophilic) Visibility Tinted Daily Disposable Contact Lens are substantially equivalent to SAUFLON 55UV (methafilcon A) Soft (hydrophilic) Visibility Tinted Contact Lenses for Daily Wear that received market clearance pursuant to K013649 and are currently marketed in the USA.

DESCRIPTION of the DEVICE:

The SAUFLON New Day® (methafilcon A) Soft (Hydrophilic) Visibility Tinted Daily Disposable Contact Lenses are available in an aqua visibility tint. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate

(HEMA) and methacrylic acid, which is cross-linked with ethyleneglycol dimethacrylate. When hydrated the lens consists of 45% HEMA and 55% water by weight of saline immersed in normal saline. The lens is visibility tinted aqua with Reactive Blue No. 4 and Reactive Yellow Dye # 86. A benzophenone UV absorbing monomer is used to block UV radiation. Sauflon New Day lenses are daily disposable lenses.

The average transmittance characteristics are less than 10% in the UVB range of 280 to 315nm and less than 40% in the UVA range of 315-380nm.
The SAUFLON New Day Daily Disposable Lens is a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

Chord Diameter:	14.0mm to 15.0mm
Centre Thickness @ -3.00DS:	0.07mm
Base Curve:	8.70mm
Powers:	-20.00 to +20.00 Presently available: -0.50 to -6.00 (0.25DS steps) -6.00 to -10.00 (0.50DS steps) +0.50 to +6.00 (0.25DS steps)
The physical/optical properties of the lens are:	
Refractive Index:	1.40 +/- 0.32
%Transmittance @ 590nm	94.61
% Transmittance @ 280-315nm	9.41
% Transmittance @ 316-380nm	36.00
Surface Character:	Hydrophilic
Water Content:	55%
Specific Gravity	1.09
Oxygen Permeability (Dk): (Fatt Method for determination of oxygen permeability)	22.0×10^{-11} (cm^2 / sec) (ml O_2 / ml x mm Hg) at 35°C

The table overleaf Table 7.1 Comparison of Physical / Optical Properties and Processes for the SAUFLON NEW DAY (methafilcon A) Soft (Hydrophilic) Daily Disposable Visibility Tinted contact lens VS. Sauflon 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear shows the rationale for substantial equivalence between the predicate device Sauflon 55UV and the Sauflon New Day Lens.

This substantial equivalence is based on the lens having the same indications for use, being equivalent in terms of performance and sharing the same chemical composition while utilising the same manufacturing method, sterilisation and packaging processes. The lens material Methafilcon A utilised by both predicate and test device was shown to be non-toxic in all cytotoxicity, systemic toxicity and ocular irritation tests as well as no residual monomers or dyes being present during leachability studies.

The predicate device Sauflon 55UV has an established shelf-life of 5 years based on both accelerated and real time stability studies presented in K013649

The rationale for these studies being applicable to the Sauflon New Day is that the same materials and processes are used for manufacture and packaging and there is no reason to believe that this lens cannot exceed the already established shelf-life.

The lens do vary in design in that the Sauflon 55UV lens is of spherical design while the Sauflon New Day lens is aspheric. This design alteration does not affect the safety or the efficacy of the lens. The design engineering drawing for the aspheric design is included in Section 8 of this submission.

Due to the varying modality of the predicate i.e. a daily wear lens and subject lens i.e. a daily disposable lens the labelling of the package insert does vary in that the package insert for a daily disposable is not required to contain as much detail as a daily wear lens requires. Items such as a cleaning and care regime for the lenses are not required as the New Day lens is disposed of following use.

The package insert does however contain all necessary information for the safe and effective use of a daily disposable lens including lens handling, insertion, removal and precautions.

The final draft labelling for the Sauflon New Day lens blister pack, carton, patient instructions and professional fitting and information guide are included in Section 5 of this submission. The patient instructions for the predicate device are included in Section 6 of this submission.

Table 7.1. Comparison of Physical / Optical Properties and Processes for the SAUFLON NEW DAY (methafilcon A) Soft (Hydrophilic) Daily Disposable Visibility Tinted contact lens VS. Sauflon 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear.

	PREDICATE DEVICE - SAUFLON 55UV (K013649)	**SUBJECT DEVICE - SAUFLON NEW DAY**
LENS DESCRIPTION	(Methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens	Identical
INDICATIONS FOR USE	Myopia, Hyperopia and Astigmatism	Identical
MODALITY	Daily Wear	Daily Disposable wear
LABELLING	Follows the recommendations given in the guidance document for Daily Wear Soft Contact lenses issued by FDA in May 1994. Labelling has been provided for lens blister, carton, Patient Instructions and Professional Fitting and Information guide suitable for a daily wear lens.	Due to the fact that these are daily disposable lenses and not daily wear lenses the labelling has been tailored for this and areas such as care regime or replacement programmes of the lenses are not relevant and therefore have not been included. Labelling has been provided for lens blister, carton, Patient Instructions and Professional Fitting and Information guide suitable for a daily disposable lens.
LENS MATERIAL	Methafilcon A	Identical
WATER CONTENT	55%	Identical
%TRANSMITTANCE @590NM %TRANSMITTANCE @280–315NM % TRANSMITTANCE @316 - 380NM	94.61% 9.41% 36.00%	Identical
DK @35^{O}C (EDGE CORRECTED)	22.0 x 10^{-11}	Identical
POWERS	-20.00 to +20.00 D	Identical

Table 7.1. Comparison of Physical / Optical Properties and Processes for the SAUFLON NEW DAY (methafilcon A) Soft (Hydrophilic) Daily Disposable Visibility Tinted contact lens VS. Sauflon 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear.

	PREDICATE DEVICE - SAUFLON 55UV (K013649)	SUBJECT DEVICE -SAUFLON NEW DAY
COLOUR	Aquamarine Visibility	Identical
REFRACTIVE INDEX	1.4020	Identical
TENSILE STRENGTH	1.47	Identical
MODULUS	0.52	identical
ELONGATION AT BREAK	280	Identical
TOUGHNESS	1.39	Identical
LENS DESIGN	Spherical	Aspherical
CHEMICAL COMPOSITION OF`FINISHED LENS	Methafilcon A which is a copolymer of 2-hydroxyethylomethacrylate and methacrylic acid cross linked with ethyleneglycol dimethacrylate. with benzophenone type UV absorbing monomer, 2-(4-benzoyl-3-hydroxyphenoxy) ethyl acrylate.	Identical
RAWMATERIAL SPECIFICATIONS	Copies of all the raw material specifications were included and approved in K013649	Identical
MANUFACTURING PROCESS	Cast Moulding	Identical

Table 7.1. Comparison of Physical / Optical Properties and Processes for the SAUFLON NEW DAY (methafilcon A) Soft (Hydrophilic) Daily Disposable Visibility Tinted contact lens VS. Sauflon 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear.

	PREDICATE DEVICE - SAUFLON 55UV (K013649)	**SUBJECT DEVICE - SAUFLON NEW DAY**
TINTING PROCESS	'In monomer' tinting	Identical
TINT USED	CI Reactive Blue Dye 4 CI Reactive Yellow Dye 86	Identical
PACKAGING MATERIALS	Injected molded polypropylene blisters covered by aluminium foil laminate and blister strips are packed into printed cartons	Identical
LENS PACKING SOLUTION	0.9%w /v sodium chloride solution buffered at pH 7.5 to 7.8 with sodium hydrogen carbonate and containing 0.005% w/v poloxamer 407	Identical
PACKAGING METHOD	Hermetically sealed blister pack	Identical
STABILITY TESTS	Real time studies (5 years at 20°C) and accelerated stability studies (45°C) carried out. All parameters including sterility remained within specification.	These studies are applicable to the New Day lens.
LEACHABILITY STUDIES–RESIDUAL MONOMERS	Residual Monomers were analysed by HPLC. The levels of monomers were below detection limits	As the material used in the two lenses i.e. Methafilcon A and the composition of the lenses are identical this leachability data is therefore applicable.

Table 7.1. Comparison of Physical / Optical Properties and Processes for the SAUFLON NEW DAY (methafilcon A) Soft (Hydrophilic) Daily Disposable Visibility Tinted contact lens VS. Sauflon 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear.		
	PREDICATE DEVICE - SAUFLON 55UV (K013649)	**SUBJECT DEVICE - SAUFLON NEW DAY**
LEACHABILITY STUDIES – COLOUR ADDITIVES	No detectable amounts of the dyes were found in the extract tested.	As the dyes used in the New Day lens is identical to those used for Sauflon 55UV lens the leachability data is therefore applicable.
STERILISATION METHOD	Sterilised in an autoclave by Steam Sterilisation	Identical
SHELF-LIFE	Shelf-life is 5 years based on stability studies	Identical
TOXIOCOLOGY OF THE LENS	The lens material Methafilcon A was shown to be non-toxic in all cytotoxicity, systemic toxicity and ocular irritation tests.	The identical lens material is utilised therefore the toxicity data is applicable.
TOXICOLOGY OF THE BLISTER PACKS	The moulded polypropylene blister material was shown to be non-toxic in all cytotoxicity, systemic toxicity and ocular irritation tests.	The identical materials are utilised in the packaging of the Sauflon New Day lens therefore the toxicity data is applicable.

PRECLINICAL TESTING

The results of toxicology testing (cytotoxicity, acute systemic toxicity and acute ocular irritation) show the lens material methafilcon A to be non-toxic and non-irritating. Furthermore, the results of residual monomer and colour leachability testing demonstrate that the respective extracts did not contain significant levels of leachable colour or residual monomers.

The physical optical, and chemical properties of the SAUFLON New Day® Daily Disposable Lenses (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens are equivalent to those of Sauflon 55 UV (methafilcon A) Soft Hydrophilic Visibility Tinted Contact Lens for Daily Wear. This lens is in group 4, Ionic, high water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994.

The lens will be sterilised and packaged in the same manner as previously cleared in K013649. This lens will also be sterility released by parametric release, as cleared in K013649.

INDICATIONS FOR USE

The SAUFLON New Day® Daily Disposable Lenses (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens is a daily disposable lens indicated for the correction of the refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres that does not interfere with visual acuity.
The predicate device Sauflon 55UV lens is prescribed for daily wear however the Sauflon New Day is a Daily Disposable lens.
The New Day lens is a convenient alternative to a daily wear lens as the patient can dispose of the lens at the end of the day and then insert a brand new pair the next morning.
This eliminates the need for the patient to carry out a cleaning regime for the lens and the risk of experiencing contact lens related problems is reduced due to the limited exposure time of using one particular set of lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sauflon Pharmaceuticals, Ltd.
c/o Ms. Tanya Fair
49-53 York Street
Twickenham, Middlesex
TW1 3LP, United Kingdom

MAY 15 2006

Re: K052832
Trade/Device Name: Sauflon New Day® (methafilcon A) Soft (Hydrophilic) Visibility Tinted Daily Disposable Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lenses
Regulatory Class: II
Product Code: MVN; LPL
Dated: May 4, 2006
Received: May 4, 2006

Dear Ms. Fair:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K052832

Device Name: SAUFLON New Day (methafilcon A) Soft (Hydrophilic) Visibility Tinted Daily Disposable Contact Lens

Indications For Use: The Sauflon New Day® (methafilcon A) Soft (hydrophilic) Visibility tinted contact lens is a daily disposable lens indicated for the correction of the refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres that does not interfere with visual acuity.

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

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

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

Mary-Ann Shri

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

510(k) Number K052832