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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: K071203

Applicant information:

Date Prepared:	April 25, 2007
Name:	Optikem International, Inc.
Address	2172 South Jason Street Denver, CO 80223
Contact Person:	Ms. Sally Cook President
Phone number:	(303) 936-1137
USA Consultant:	MedVice Consulting, Inc. Mr. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501
Email address:	marty@FDApproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPN 886.5928
Classification Name:	Accessories, soft lens products Soft (hydrophilic) contact lens care products

Trade Name: **Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses**

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Purpose of 510(k) Submission:

New Device

Optikem International, Inc. proposes to market and sell in United States interstate commerce, The Sereine Extra Strength Daily Cleaner for use with Silicone Hydrogel contact lens material. Data supporting the safety and effectiveness of cleaning Silicon Hydrogel contact lens materials are included in this submission. The Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is the same solution as cleared in 510(k) K011561.

Equivalent Devices:

The Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is the same solution as cleared in 510(k) K011561, which is substantially equivalent to the MIRAFLOW cleaner by CIBA Vision. The Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is substantially equivalent in terms of its actions, and formulation.

PREDICATE DEVICE ~

- The **Sereine Extra Strength Daily Cleaner** Manufactured by Optikem International, Inc.

Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Device Description:

Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is a sterile, viscous, aqueous solution with an alkaline pH. The cleaner contains no added preservatives. The cleaner contains an amphoteric surfactant to aid in the removal of film, deposits and other debris that accumulates on contact lenses during wear. The cleaner is not meant for use in the eye and must be thoroughly rinsed from the lenses.

Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is packaged in a 1 FL OZ plastic bottle (polyethylene) with red dropper tip (polyethylene) and white over-cap (polypropylene). It has an outside cardboard carton. It has an expiration date of two years from the date of bottling.

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Intended Use:

The intended use of the device is as a daily cleaner or the removal of proteins, lipids and other debris that accumulates on contact lenses during wear. The device is to be used for the removal of this debris immediately after the lenses are removed from the eye. The device is intended for use as a cleaner with Silicone Hydrogel contact lenses. The device is not intended for use in the eye and must be physically rinsed from the lens using either saline solution or multipurpose solution cleared for use on Silicone Hydrogel prior to insertion.

Pre-Clinical Performance Data:

Data to demonstrate the safety and effectiveness of the Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses when used to clean Silicone Hydrogel contact lenses are included in this submission and supported by the following studies:

- **30 day Silicone Hydrogel compatibility study**

  A study was conducted to test the compatibility of Sereine Extra Strength Daily Cleaner on Silicone Hydrogel soft lens parameters. Four Silicone Hydrogel contact lens types were tested: senofilcon A, lotrafilcon A, comfilcon A, and balafilcon A. A baseline of parameters was measured using ISO standard 81369-2, and none of the lenses showed a change in baseline parameters as well as none of the lenses showed discoloration or any change in lens clarity. It was concluded that the Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is physically compatible with senofilcon A, lotrafilcon A, comfilcon A, and balafilcon A lenses.

Product Name	Lens Type (USAN)	Parameter Change 15 days	Parameter Change 30 days	Color Change
OASYS	senofilcon A	No Change	No Change	No Change
Night & Day	lotrafilcon A	No Change	No Change	No Change
Biofinity	comfilcon A	No Change	No Change	No Change
Purevision	balafilcon A	No Change	No Change	No Change

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- **Cytotoxicity studies – ISO Direct Contact Test**

  Studies were conducted on the four Silicone Hydrogel lenses after a 30 day regime cleaning period with the Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses. It was concluded that the lenses met ISO requirements for Cytotoxicity.

All other safety and efficacy data can be referenced in previously cleared 510(k) K011561. Permission to reference 510(k) K011561 is included in this 510(k).

Substantial Equivalence:

The Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is substantially equivalent to the following predicate devices:

- The **Sereine Extra Strength Daily Cleaner** Manufactured by Optikem International, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optikem International, Inc.
c/o Mr. Martin Dalsing
MedVice Consulting, Inc.
2214 Sanford Drive, Unit B7
Grand Junction, CO 81505

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Re: K071203
Trade/Device Name: Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SiHy) Soft Contact Lenses
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: April 25, 2007
Received: May 1, 2007

Dear Mr. Dalsing:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

MB Eydelman, MD

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

Device Name: Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses

INDICATIONS FOR USE:

The Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is a cleaner for removal of film, deposits and other accumulated debris, which accumulate on Silicone Hydrogel soft contact lenses during wear.

Sereine Extra Strength Daily Cleaner for Silicone Hydrogel (SIHY) Soft Contact Lenses is to be used with a Multipurpose Solution indicated for Silicone Hydrogel soft contact lenses. Follow the recommendation of your eye care practitioner when disinfecting your lenses.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071203

Prescription Use ____ (Per 21 CFR 801.109)

or

Over-The-Counter Use X

(Optional Format 1-2-96)