K090725
Page 1 of 3

MAY 20 2009

Oculus Innovative Sciences
1135 N. McDowell Blvd.
Petaluma, CA 94954

-CONFIDENTIAL-

510(K) SUMMARY

5.1 Sponsor Information

Company Information:	Oculus Innovative Sciences, Inc. 1135 North McDowell Blvd. Petaluma, CA 94954 (707) 283-0550 (707) 283-0551
Contact Information:	Antoinette Douglas Associate Director, Regulatory Affairs Phone: (707) 559-2445 Email: adouglas@oculusis.com
Date of Preparation:	February 2009

5.2 Device Information

Device Trade Name:	Oculus Microcyn™ Wound Gel
Common Name:	Wound Gel
Classification Name:	Dressing, wound and burn drug/ hydrogel
Device Class:	Unclassified
Device Code:	FRO
Advisory Panel :	TBD

5.3 Identification of Legally Marketed Device for Substantial Equivalence Comparison

Oculus Microcyn™ Skin and Wound Gel Solution is substantially equivalent to the following cleared predicate device:

LAM I.P.M.™ Wound Gel Cleanser originally manufactured by L.A.M Pharmaceutical Corp., cleared for distribution under 510(k) K020325.

5.4 Device Description

Oculus Microcyn™ Skin and Wound Gel is a clear viscous, odorless, aqueous hydrogel. The gel will be supplied in 2 oz polyethylene terephthalate bottles with polypropylene disc top caps as described in Section 11.3.

Oculus Microcyn™ Skin and Wound Gel has been subjected to in-vitro and in-vivo biocompatibility testing (cytotoxicity, dermal irritation and dermal sensitization). These tests results demonstrate the Oculus Microcyn™ Skin and Wound Gel is a safe for use as temporary dressing when in contact with abraded, breached or compromised skin. Clinical experience with the solution form of the product indicates the Oculus Microcyn™ Skin and Wound Gel is safe for its intended use.

5.5 Intended Use

Oculus Microcyn™ Skin and Wound Gel is intended for over-the counter (OTC) and professional use as follows:

OTC: Oculus Microcyn™ Skin and Wound Gel is intended for over the counter use for minor skin abrasions, lacerations, minor irritations and intact skin.

Professional Use: Under the supervision of a healthcare professional, Oculus Microcyn™ Skin and Wound Gel is intended for exuding wounds such as leg ulcers, pressure ulcer, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

These indications are similar to that of the predicate device (LAM I.P.M.™ Wound Gel) cleared on April 15, 2002.

5.6 Device Technological Characteristics

Oculus Microcyn™ Wound Gel is a clear, aqueous hydrogel that exhibits the capacity to absorb moisture and control wound exudate. Hydrogel characteristics are imparted by an inert viscosity enhancing agent. Oculus wound gel maintains a moist wound environment that supports the wound healing process by encouraging autolytic debridement. Oculus Microcyn™ wound gel protects against dehydration, contamination and absorbs wound exudates.

5.7 Manufacturing:

Oculus Microcyn™ Skin and Wound Gel will be manufactured under the guidelines of Good Manufacturing Practices (GMPs) and according to the

K090725
page 3073

established manufacturing, quality and product specifications as detailed in CFR 820. The manufacturing process will be validated before commercial production begins. Established cGMPs procedures will assure that device manufactured at Oculus Innovative Science meet all the established specifications prior to release and is safe and effective for its intended use.

Performance Testing:

Oculus Microcyn™ Skin and Wound Gel has been subjected to in-vitro and in-vivo biocompatibility studies to demonstrate that the device is safe for the indications for use. Extensive bench, biocompatibility and animal testing have been performed to support the safety and efficacy of the Oculus Microcyn™ Skin and Wound Gel. All of the testing showed that the gel functions as intended without adverse effects. Oculus Microcyn™ Skin and Wound Gel has been evaluated in accordance with the International Standard Organization (ISO), Part 10 993 which includes testing for cytotoxicity and sensitization. USP Antimicrobial Effectiveness Testing <51> was performed to support claims that the FAC inhibits contamination within the hydrogel. Extrapolated results from ongoing stability studies support a product shelf life of 18 months.

5.8 Substantial Equivalence Discussion/ Conclusion

Oculus Microcyn™ Skin and Wound Gel is similar in function and has the same intended use as the predicate device LAM I.P.M.™ Wound Gel (originally LAM Pharmaceuticals), that is legally marketed under 510(k) K020325 as a wound gel. The safety evaluation meets the requirements as detailed by USP and ISO. Safety has been established through biocompatibility testing, in-vitro Cytotoxicity testing and sensitization testing in species across two species of animal.

On the basis of the information presented in this application, Oculus Innovative Sciences concludes that Oculus Microcyn™ Skin and Wound Gel is safe and effective for its use and is substantially equivalent to the predicate device as it as has the same intended use as the predicate; has different technological characteristics and the information submitted to FDA which does not raise new questions of safety and effectiveness; and demonstrates that the device is at least as safe and effective as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Oculus Innovative Sciences, Inc.
% Ms. Antionette Douglas
Associate Director, Regulatory
Affairs & Quality
1135 N. McDowell Boulevard
Petaluma, California 94954

Re: K090725
Trade/Device Name: Oculus Microcyn Skin Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 21, 2009
Received: April 30, 2009

Dear Ms. Douglas:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oculus Innovative Sciences
1135 N. McDowell Blvd.
Petaluma, CA 94954

Indications for Use

510(k) Number (if known): K090725

Device Name: Oculus Microcyn Skin Wound Gel

Indications For Use:

OTC: Oculus Microcyn Skin and Wound Gel is intended for OTC use for the management of minor skin abrasions, lacerations, cuts and intact skin.

Professional Use: Under the supervision of a health care professional, Oculus Puracyn Wound Gel is intended for the management of exuding wounds such as leg ulcers, pressure ulcer, diabetic ulcers and for the management of mechanically or surgically debrided wounds.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090725