Oculus Innovative Sciences
1129 N. McDowell Blvd.
Petaluma, CA 94954

FEB - 2 2011

5.0 510(K) SUMMARY

5.1 Sponsor Information

Company Information:	Oculus Innovative Sciences, Inc. 1129 North McDowell Blvd. Petaluma, CA 94954 Phone (707) 283-0550
Contact Information:	Antoinette Douglas Director, Regulatory Affairs and Quality Assurance Phone: (707) 559-2445 Fax: (414) 462-5163 Email: adouglas@oculusis.com
Date of Preparation:	January 2011

5.2 Device Information

Device Trade Name:	Epicyn™ HydroGel
Common Name:	Hydrogel Wound Dressing
Classification Name:	Dressing, wound and burn drug/ hydrogel
Device Class:	Unclassified
Device Code:	MGQ
Advisory Panel :	TBD

5.3 Identification of Legally Marketed Device for Substantial Equivalence Comparison

Epicyn™ HydroGel is substantially equivalent to the following cleared predicate devices:

- Sinclair Wound and Skin Emulsion currently marketed as Atopiclair® manufactured by Sinclair Pharmaceuticals, Ltd., cleared for distribution via 510(k) K090092 on July 28, 2003 (Appendix 2).

- Microcyn Skin and Wound HydroGel manufactured by Oculus Innovative Sciences, cleared for distribution via 510(k) K093585 on March 09, 2010 (Appendix 3).

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5.4 Device Description

Epicyn™ HydroGel is an emollient containing, non oily pH neutral hydrogel. The product is preserved with a unique mixture of hypochlorous acid and sodium hypochlorite generated through a proprietary process. The gel forms a protective barrier which retains moisture and provides relief of the burning and itching associated with various types of dermatoses including atopic dermatitis. The gel will be supplied in polyethylene terephthalate (PET) tube-bottles with polypropylene (PP) tamper resistant snap-top closure as described in Section 11.3.

Epicyn™ HydroGel has been subjected to in-vitro and in-vivo biocompatibility testing (cytotoxicity, dermal irritation and dermal sensitization). These tests results demonstrate that Epicyn™ HydroGel is a safe for use when in contact with abraded, breached or compromised skin.

5.5 Intended Use

Epicyn™ HydroGel is proposed for the following use:

Professional Use:
Under the supervision of a health care professional, Epicyn™ HydroGel is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis. Epicyn HydroGel may be also used to relieve the pain of first and second degree burns. Epicyn HydroGel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

These indications are similar to that of the predicate device (Sinclair Wound and Skin Emulsion) cleared on July 28, 2003.

5.6 Device Technological Characteristics

Epicyn™ HydroGel is a clear, aqueous hydrogel that exhibits the capacity to control moisture and control wound exudate. Hydrogel characteristics are imparted by an inert viscosity enhancing agent and an emollient. Epicyn™ HydroGel maintains a moist wound environment that supports the wound healing process by encouraging autolytic debridement. The hydrogel barrier manages pain and itch by protecting the wound from contamination and irritation.

5.7 Manufacturing:

Epicyn™ HydroGel will be manufactured under the guidelines of Good Manufacturing Practices (GMPs) and according to the established manufacturing, quality and product specifications as detailed in CFR 820. The manufacturing

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process will be validated before commercial production begins. Established cGMPs procedures will assure that devices manufactured at Oculus Innovative Science meet all established specifications prior to release and are safe and effective for its intended use.

Performance Testing:
Epicyn™ HydroGel 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 testing including bioburden, biocompatibility and animal testing have been performed to support the safety and efficacy of the Epicyn™ HydroGel. Test results demonstrate that the gel functions as intended and without adverse effects. Epicyn™ HydroGel has been evaluated in accordance with the International Standard Organization (ISO), Part 10993-1 which includes testing for cytotoxicity and sensitization. USP Antimicrobial Effectiveness Testing <USP 51> and Microbial Enumeration testing <USP 61> characterization studies were performed to support claims that the FAC inhibits contamination within the hydrogel. Extrapolated results from ongoing stability studies support a product shelf life of 12 months.

5.8 Substantial Equivalence Discussion/ Conclusion

Epicyn™ HydroGel is similar in function and has the same intended use as the predicate device Sinclair Wound and Skin Emulsion (Atopiclair) manufactured by Sinclair Pharmaceuticals. The predicate device is legally marketed via 510(k) K024367. The safety evaluation meets the requirements as detailed by ISO 10993-1. 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 Epicyn™ HydroGel 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Oculus Innovative Sciences, Inc.
% Ms. Antoinette Douglas
Director, Regulatory and Quality Assurance
1129 North McDowell Boulevard
Petaluma, California 94954

FEB - 2 2011

Re: K102945
Trade/Device Name: Epicyn HydroGel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 26, 2011
Received: January 27, 2011

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

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Indications for Use

510(k) Number (if known): K102945

Device Name: Epicyn HydroGel

Indications For Use:

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Prescription Use XX AND/OR Over-The-Counter Use N/A
(Part 21 CFR 801 Subpart D) (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 K102945