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

MAR - 8 2010

5.0 510(K) SUMMARY

5.1 Sponsor Information

Company Information:	Oculus Innovative Sciences, Inc. 1129 North McDowell Blvd. Petaluma, CA 94954 (707) 283-0550 (707) 283-0551
Contact Information:	Antoinette Douglas Director, Regulatory Affairs Phone: (707) 559-2445 Email: adouglas@oculusis.com
Date of Preparation:	November 2009

5.2 Device Information

Device Trade Name:	Microcyn™ Skin and Wound HydroGel
Common Name:	Hydrogel Wound Dressing
Classification Name:	Dressing, wound and burn drug/ hydrogel
Device Class:	Unclassified under 21 CFR Parts 862-892
Device Code:	FRO
Advisory Panel :	TBD

5.3 Identification of Legally Marketed Device for Substantial Equivalence Comparison

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

- SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel manufactured by McMerlin Dental Products, LP, cleared for distribution via 510(k) K090092 on September 9, 2009.

- Oculus Microcyn Skin and Wound Gel manufactured by Oculus Innovative Sciences, cleared for distribution via 510(k) K090725 on May 22, 2009 (Appendix 3)

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5.4 Device Description

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

Microcyn™ Skin and Wound HydroGel has been subjected to in-vitro and in-vivo biocompatibility testing (cytotoxicity, dermal irritation and dermal sensitization). These tests results demonstrate the Microcyn™ Skin and Wound HydroGel 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 Microcyn™ Skin and Wound HydroGel is safe for its intended use.

5.5 Revised Intended Use

Microcyn™ Skin and Wound HydroGel is proposed for the following uses:

Over-the -Counter:
Microcyn Skin and Wound HydroGel is intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns. Microcyn is also indicated for the management of irritation and pain from minor sunburn.

Professional Use:
Under the supervision of a healthcare professional, Microcyn Skin and Wound Hydro-Gel is intended for management of wounds including itch and pain relief associated with dermal irritation, sores, injuries and ulcers of dermal tissue. Microcyn Skin and Wound HydroGel is intended for use on first and second degree burns, exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

These indications are similar to that of the predicate device (SockIt!®/ McMerlin Dermal Wound Gel) cleared on September 09, 2009.

5.6 Device Technological Characteristics

Microcyn™ Wound HydroGel 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. Microcyn™ wound gel protects against dehydration,

contamination and absorbs wound exudates. The hydrogel barriers manages pain by protecting the wound from contamination and irritation.

5.7 Manufacturing:

Microcyn™ Skin and Wound 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 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 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 Microcyn™ Skin and Wound HydroGel. All of the testing showed that the gel functions as intended without adverse effects. Microcyn™ Skin and Wound HydroGel 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

Microcyn™ Skin and Wound HydroGel is similar in function and has the same intended use as the predicate device SockIt!®/McMerlin Dermal Wound Gel (manufactured by McMerlin Dental Products), that is legally marketed under 510(k) K090092 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 Microcyn™ Skin and Wound HydroGel is safe and

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Oculus Innovative Sciences, Inc.
% Ms. Antoinette Douglas
Director, Regulatory Affairs
1135 North McDowell Boulevard
Petaluma, California 94954

Re: K093585
Trade/Device Name: Microcyn Skin and Wound HydroGel
Regulatory Class: unclassified
Product Code: FRO
Dated: March 3, 2010
Received: March 5, 2010

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,

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

Enclosure

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

Indications for Use

510(k) Number (if known): K093585

Device Name: Microcyn Skin and Wound HydroGel

Indications For Use:

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OTC:

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Prescription Use XX AND/OR Over-The-Counter Use XX
(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)

Daniel Krause for MKal

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

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