510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

510(k) Owner
Oculus Innovative Sciences, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954
Phone: (707) 283-0550
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NOV 15 2013

Official Contact
Brian W. Martin
Director of Regulatory Affairs and Quality Control

Device Information

Trade or Proprietary Name:	Microcyn® Scar Management HydroGel
Common Name:	Silicone Scar Gel
Classification Name:	Elastomer, Silicone, for Scar Management
Regulation:	Class I per 21CFR §878.4025
Product Code(s)	PFP
Legally marketed device(s) to which equivalence is claimed:	Kelo-Cote Topical™ Gel manufactured by Advanced Bio-Technologies, cleared for distribution via 510(k) K002488 Beau Rx Scar Care Gel currently marketed as Atopiclair® manufactured by Beau Rx Solutions, LLC, cleared for distribution via 510(k) K083718
Reason for 510(k) submission	New Device
Device Description	Microcyn® Scar Management HydroGel is a translucent, silicone oil containing hydrogel which is intended for the management of old and new scars including hypertrophic and keloid scarring, on scars resulting from general surgical procedures, as well as trauma wounds, and burns. The product is intended to be applied to intact skin. The product is preserved with a unique mixture of hypochlorous acid and sodium hypochlorite generated through a proprietary process. The mixture of hypochlorous acid and sodium hypochlorite act as a preservative in the non-sterile product to inhibit microbial growth during storage and repeat use. The preservative is identified by the Center for Drug Evaluation and Research (CDER) as an inactive ingredient based on the

	concentration. The gel will be supplied in polyethylene terephthalate (PET) tube-bottles with polypropylene (PP) tamper resistant snap-top closure.
Intended Use	Rx INDICATIONS: Under the supervision of a health care professional, Microcyn® Scar Management HydroGel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. OTC INDICATIONS: Microcyn® Scar Management HydroGel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.
Performance Testing	The Microcyn® Scar Management HydroGel meets specification and performance characteristics and is substantially equivalent to the predicate device.
Biocompatibility Testing	Biocompatibility Testing of the Microcyn® Scar Management HydroGel confirmed that the device meets the applicable requirements of the Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of Medical Devices and is biocompatible.
Clinical Testing	The Microcyn® Scar Management HydroGel was well tolerated in the study population and efficacy results indicate substantial equivalence to the predicate device, Kelo-cote® Scar Gel.
Safety and Effectiveness	The Microcyn® Scar Management HydroGel does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed.
Substantial Equivalence (SE) Rationale	The Microcyn® Scar Management HydroGel is substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the Kelo-Cote Topical™ Gel and Beau Rx Scar Care Gel. Therefore, the Microcyn® Scar Management HydroGel is substantially equivalent to the predicate devices.
Submitted by:	Brian W. Martin Director of Regulatory Affairs and Quality Control
Date Submitted:	11/13/2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 15, 2013

Oculus Innovative Sciences
Mr. Brian W. Martin
Director of Regulatory Affairs and Quality Control
1129 North McDowell Boulevard
Petaluma, California 94954

Re: K131672
Trade/Device Name: Microcyn® Scar Management HydroGel
Regulation Number: 21 CFR 878.4025
Regulation Name: Elastomer, Silicone, for Scar Management
Regulatory Class: Class I
Product Code: PFP
Dated: September 24, 2013
Received: October 1, 2013

Dear Mr. Martin:

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 contact 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. 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,

David Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131672

Device Name
Microcyn® Scar Management HydroGel

Indications for Use *(Describe)*
Rx INDICATIONS: Under the supervision of a health care professional, Microcyn® Scar Management HydroGel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.
OTC INDICATIONS: Microcyn® Scar Management HydroGel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S