DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 19, 2016

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

Re: K153648
Trade/Device Name: Microcyn Plus Skin And Wound Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 16, 2016
Received: March 18, 2016

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 Binita S. Ashar, M.D., M.B.A., F.A.C.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153648

Device Name
Microcyn Plus Skin and Wound HydroGel

Indications for Use *(Describe)*

Rx Indications for Use:

Under the supervision of a health care professional Microcyn Plus Skin and Wound Gel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

OTC Indications for Use:

Microcyn Plus Skin and Wound Gel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Plus Skin and Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

I. SUBMITTER

Oculus Innovative Sciences, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954

Phone: (707) 283-0550
Fax: (707) 283-0551

Contact Person: Brian W. Martin, Director of Regulatory Affairs and Quality Control
Date Prepared: December 18, 2014

II. DEVICE

Name of Device: Microcyn Plus Skin and Wound Hydrogel
Common or Usual Name: Wound Gel
Classification Name: Hydrogel Wound Dressing
Regulatory Class: Unclassified, Pre-amendment status
Product Code: FRO

III. PREDICATE DEVICE

Microcyn Skin and Wound Gel manufactured by Oculus Innovative Sciences (K093585)
Sockit Dermal Wound Gel manufactured by McMerlin Dental Products (K090092)

IV. DEVICE DESCRIPTION

The Microcyn Plus Skin and Wound Hydrogel is a clear gel, slightly chlorinated odor, viscous gel. The product has a pH range of 6.2-7.8 and a viscosity target of 12,000-20,000 cP and will be supplied in polyethylene terephthalate (PET) tube-bottles with polypropylene (PP) screw-top closure.

V. INDICATIONS FOR USE

Rx Indications for Use:
Under the supervision of a health care professional Microcyn Plus Wound Gel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

OTC Indications for Use:
Microcyn Plus Wound Gel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	**Proposed Device:** **Microcyn Plus Hydrogel** **Oculus Innovative Sciences**	**Predicate Device: K093585** **Microcyn Skin and Wound Hydrogel** **Oculus Innovative Sciences**	**Predicate Device: K090092** **Sockit Dermal Gel** **McMerlin Dental Products**
Indications for Use	Rx Indications for Use: Under the supervision of a health care professional Microcyn Plus Wound Gel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns. OTC Indications for Use: Microcyn Plus Wound Gel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.	Rx Indications for Use: Under the supervision of a healthcare professional, Microcyn Skin and Wound HydroGel 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 mechanically or surgically debrided wounds. OTC Indications for Use: 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.	Rx Indications for Use: This product provides for the management of and relieves the pain associated with all types of dermal wounds, skin sores, injuries and ulcers of the skin. Examples include: • All types of dermal wounds, skin sores, injuries and ulcers of the skin • First & Second degree burns • Pressure ulcers, stages I - IV • Stasis ulcers • Diabetic ulcers • Radiation dermatitis • Post-surgical incision • Surgical sites, including soft tissue graft sites • Foot ulcers • Venous stasis ulcers • Cuts & Abrasions • Partial thickness wounds • Irritation of the skin • Itching • Sunburn • Skin condition associated periostomy care • Chemical peel • Tattooing procedures • Irritation and pain following skin Laser resurfacing treatment • Irritation and pain following dermabrasion therapy OTC Indications for Use: This product provides for the management of

Submitter/ Holder	Proposed Device: Microcyn Plus Hydrogel Oculus Innovative Sciences	Predicate Device: K093585 Microcyn Skin and Wound Hydrogel Oculus Innovative Sciences	Predicate Device: K090092 Sockit Dermal Gel McMerlin Dental Products
			and relieves the pain associated with all minor dermal wounds, minor skin sores, minor injuries and minor irritations of the skin. Examples include: • Minor burns • Minor Cuts & Abrasions • Superficial itching • Sunburn • Minor burns from a chemical peel treatment • Minor irritation and pain following tattooing procedures • Minor irritation and pain following skin laser resurfacing treatment • Minor irritation and pain following dermabrasion therapy
Sterility Claim	Non-sterile Preserved/Conforming to USP <51>	Same	Non-sterile Natural Preservative Gel from food grade components
Mechanism of Action	Wound Barrier and moisturizer	Same	Same
Delivery System	Hydrogel	Same	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
The biocompatibility evaluation for the Microcyn Plus Hydrogel was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The solution is considered a breached/compromised surface device with limited contact.

Study Title	Summary
Agar Diffusion Test –ISO	No biological reactivity (Grade 0) observed in the L929 cells at 48 hours post exposure.
Acute Dermal Toxicity – OECD	The test substance is considered non-toxic according to the study protocol criteria.
Primary Eye Irritation	Mildly irritating to the eye. No other signs of gross toxicity, adverse pharmacological effects, or abnormal behavior.
Cumulative Skin Irritation Test – FHSA	Negligible irritant – no signs of erythema or edema were noted at any observation period.
Intracutaneous Injection	Irritant when injected under the skin.
Kligman Maximization Test, Direct Contact – ISO	The test article elicited no reaction, a Grade I reaction as defined by the scoring system of Kligman, classified as having weak allergenic potential.

Bench Testing
The following tests were performed to support the performance of Microcyn Plus Hydrogel: package integrity, visual inspection, viscosity, pH, Free Available Chlorine (FAC). The Microcyn Plus Hydrogel meets specification and performance characteristics and is substantially equivalent to the predicate device.

VIII. CONCLUSION

Microcyn Plus Hydrogel is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Microcyn Skin and Wound Hydrogel manufactured by Oculus Innovative Sciences, Inc. (K093585) and Sockit Dermal Wound Gel manufactured by McMerlin Dental Products (K090092). Therefore, the Oculus Microcyn Plus Hydrogel is substantially equivalent to the predicate devices.