DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 19, 2016

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

Re: K161034
Trade/Device Name: Microcyn Plus Wound Care Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 5, 2016
Received: July 13, 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" (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 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

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)*
K161034

Device Name
Microcyn Plus Solution

Indications for Use *(Describe)*

Rx Indications:

Under the supervision of a healthcare professional, Microcyn Plus is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree bums, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications:

Microcyn Plus is intended for use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

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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"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."

1 510(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: August 11, 2016

II. DEVICE

Name of Device: Oculus Microcyn Plus Wound Care Solution
Common or Usual Name: Wound Cleanser
Classification Name: Solution, Saline, Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO

III. PREDICATE DEVICE

Oculus Hydrocleanse (K141012) and Vashe Wound Care Solution manufactured by Puricore (K131848).

IV. DEVICE DESCRIPTION

The Oculus Microcyn Plus Wound Care Solution is a colorless, slightly chlorinated odor, clear aqueous solution for moistening of wound dressings, wound debridement, and use with devices intended for wound irrigation with a pH range of 3.5 – 6.0. The solution will be supplied in 40mL glass vials with Teflon lined closures.

V. INDICATIONS FOR USE

Rx Indications:
Under the supervision of a healthcare professional, Microcyn Plus is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions

including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree bums, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications:
Microcyn Plus is intended for use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	**Proposed Device: Microcyn Plus Solution Oculus Innovative Sciences**	**Predicate Device: K141012 Hydrocleanse Wound Care Solution Oculus Innovative Sciences**	**Predicate Device: K131848 Vashe Wound Solution Puricore Inc.**
Indications for Use	**Rx Indications:** Under the supervision of a healthcare professional, Microcyn Plus is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree bums, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. **OTC Indications:** Microcyn Plus is intended for use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	**Rx Indications:** Under the supervision of a healthcare professional, Hydrocleanse ™ Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree bums, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. **OTC Indications:** Hydrocleanse ™ Solution is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	**Rx Indications:** Under the supervision of healthcare professionals, Vashe Wound Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.
Sterility Claim	Non-sterile	Same	Same
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound. Provides moisture and rehydration.	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound.	The mechanism of fluid moving across the wound aids in the physical removal of foreign objects, foreign debris and exudate from a wound.
Delivery System	Aqueous Solution	Aqueous Solution	Aqueous Solution

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 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.
Testing Completed: Cytotoxicity, Irritation, Sensitization, and Systemic Toxicity

Bench Testing
The following tests were performed to support the performance of Microcyn Plus Wound Care Solution: package integrity, visual inspection, pH, Free Available Chlorine (FAC), fill volume, USP <51> and USP<61>. The Microcyn Plus Wound Care Solution meets specification and performance characteristics and is substantially equivalent to the predicate device.

VIII. CONCLUSION

Microcyn Plus Solution is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Hydrocleanse Wound Solution manufactured by Oculus Innovative Sciences (K141012) and Vashe Wound Care Solution manufactured by Puricore (K131848). Therefore, the Microcyn Plus Solution is substantially equivalent to the predicate devices.