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**5.0 510(K) SUMMARY**

**5.1 Sponsor Information**

**Company Information:** Oculus Innovative Sciences, Inc.  
1135 North McDowell Blvd.  
Petaluma, CA 94954  
(707) 559-2445  
(707) 283-0551

**Contact Information:** Antoinette Douglas  
Director, Regulatory Affairs and Quality Assurance  
Phone: (707) 559-2445  
Fax: (415) 462-5163  
Email: [adouglas@oculusis.com](mailto:adouglas@oculusis.com)

**Date of Preparation:** May 2009

**5.2 Device Information**

**Device Trade Name:** Oculus Puracyn™ Skin and Wound Cleanser with Preservatives

**Common Name:** Wound cleanser

**Classification Name:** Dressing, wound and drug

**Device Class:** Unclassified

**Device Code:** FRO

**Advisory Panel :** TBD

**5.3 Identification of Legally Marketed Device for Substantial Equivalence Comparison**

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is substantially equivalent to the following cleared predicate device:

Anasept™ Antimicrobial Skin and Wound Cleanser manufactured by Anacapa Technologies, cleared for distribution under 510(k) K073547.

**5.4 Device Description**

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is a clear hypotonic solution that aids in the mechanical removal of the debris and foreign material from the application site. Dirt debris and foreign material are

mechanically removed by the action of the wound cleanser moving across the wound bed or application site with or without the assistance of a suitable wound dressing (i.e. gauze). The device also contains antimicrobial agents that inhibit the growth of microorganisms. Oculus Puracyn™ Skin and Wound Cleanser with Preservatives will be supplied in High Density Polyethylene (HDPE) bottles of various volumes with dosing inserts and caps as described in Section 11.3.

## 5.5 Intended Use

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is intended for over-the counter (OTC) and professional use as follows:

**OTC:** Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is intended for OTC use for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

**Professional Use:** Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is intended to be used by health care professionals in the management via debridement of wounds such as stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

These indications are similar to that of the predicate device (Anasept™ Antimicrobial Skin and Wound Cleanser) cleared on April 23, 2008.

## 5.6 Device Technological Characteristics

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is a clear, hypotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site. Dirt, debris and foreign materials are mechanically removed by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. Oculus Puracyn™ Skin and Wound Cleanser with Preservatives contains broad spectrum antimicrobial agents (sodium hypochlorite and hypochlorous acid) that inhibit the growth of bacteria such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Proteus mirabilis*, *Serratia marcescens*, including antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE) and *Acinetobacter baumannii* that are commonly found in wound bed as well as fungi such as *Candida albicans* and *Aspergillus niger*.

### **Manufacturing:**

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives will be manufactured under the guidelines of current Good Manufacturing Practices (cGMPs) and according to the established manufacturing, quality and product specifications. Process validation has been completed for this device and filling process parameters have been qualified. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. Established cGMPs will assure that the device manufactured at Oculus Innovative Sciences meet all the established specifications prior to release and is safe and effective for its intended use.

### **Performance Testing:**

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives has been subjected to in-vitro and in-vivo studies to demonstrate that the device is safe and effective for the indications for use. One series of time kill testing was performed utilizing the test organisms prescribed in the USP Antimicrobial Effectiveness <51> such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida albicans*, *Aspergillus niger* and additional bacterial strains, such as, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE), *Proteus mirabilis*, *Serratia marcescens* and *Acinetobacter baumannii* that are commonly found in wound bed. All test results indicate that the product is capable of inhibiting the growth of bacteria and reducing high level concentrations of microorganisms ( $10^7$  organisms /gram of product) to undetectable levels. The results of the stability study demonstrate that the product is stable for at least 24 months when stored at room temperature.

### **5.7 Substantial Equivalence Discussion/ Conclusion**

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is similar in function and has the same intended use as the predicate device Anasept™ Antimicrobial Skin and Wound Cleanser (Anacapa Technologies), legally marketed under 5109(k) K073547 as a dressing wound or drug.

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 of animal and mucosal irritation in two species

of animal. The mechanical mechanism of action and antimicrobial effectiveness have been demonstrated by in-vitro studies.

On the basis of the information presented in this application, Oculus Innovative Sciences concludes that Oculus Puracyn™ Skin and Wound Cleanser with Preservatives is safe and effective for its use and is substantially equivalent to the predicate device as it has the same intended use as the predicate; and 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Oculus Innovative Sciences, Incorporation  
% Ms. Antoinette Douglas  
Associate Director, Regulatory Affairs & Quality  
1135 North McDowell Boulevard  
Petaluma, California 94954

Re: K090206

Trade/Device Name: Oculus Puracyn Skin and Wound Cleanser with Preservatives  
Regulation Number: Unclassified  
Regulation Name: Unclassified  
Regulatory Class:  
Product Code: FRO  
Dated: May 13, 2009  
Received: May 15, 2009

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.

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

Page 2- Ms. Antoinette Douglas

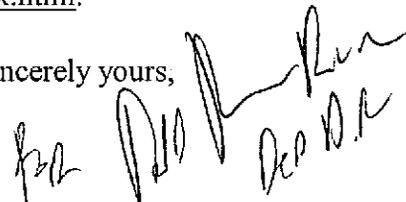
practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/cdrh/comp/> 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

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

Enclosure

### Indications for Use

510(k) Number (if known): K090206

Device Name: Oculus Puracyn Skin and Wound Cleanser with Preservatives

**Indications For Use:**

**OTC:**

Oculus Puracyn Skin and Wound Cleanser with Preservatives is intended for OTC use for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

**Prescription Use:**

Oculus Puracyn Skin and Wound Cleanser with Preservatives is intended to be used by health care professionals in the management, via debridement of wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(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 Kraneff    
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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510(k) Number   K090206