K060113

Appendix 6

2/22/06

510(k) Summary of Dermacyn™ Wound Care

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R 807.92.
Submitter	Oculus Innovative Sciences 1129 North McDowell Blvd. Petaluma, CA 94954
Contact Person	Tammy Atwood Quality Assurance Manager Tel: (707) 559-7191 Fax: (707) 782-0705 E-mail: tatwood@oculusis.com
Date Prepared	January 13, 2006
Trade Name	Dermacyn™ Wound Care
Common Name	Wound Cleanser
Classification Name	Liquid Bandage
Predicate Device	Allclenz™ Cleanser; Healthpoint Medical K965120, Mar. 21st, 1997 CarraKlenz Wound Cleanser; Carrington Laboratories, Inc. K022670, Oct. 17th, 2002
Description	The subject device is a wound cleansing solution that is intended for the moistening and debriding of dermal wounds. The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. The subject device is offered in various bottle sizes with and without a trigger spray.
Indications for Use	Dermacyn™ Wound Care is intended for moistening absorbent wound dressings and for debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, statis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin.
Substantial Equivalence	The product is similar in function and intended use to Allclenz and CarraKlenz/Ultraklenz Wound Cleansers manufactured by Healthpoint Medical and Carrington Laboratories, Inc., respectively, and includes among its labeled uses the cleansing of wounds and removal of foreign material from dermal wounds.
Non-clinical Performance	Non-clinical testing was conducted to confirm the safe and effective performance of Dermacyn™ Wound Care. Non-clinical testing also demonstrated the biocompatibility of the subject device.
Conclusion	Dermacyn™ Wound Care is substantially equivalent to the currently cleared and marketed Allclenz and CarraKlenz/Ultraklenz Wound Cleansers.

80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Oculus Innovative Sciences, Inc.
c/o Ms. Tammy Atwood
Manager, Quality Assurance
1129 N. McDowell Blvd.
Petaluma, California 94954

Re: K060113
Trade/Device Name: Dermacyn™ Wound Care
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 13, 2006
Received: January 17, 2006

Dear Ms. Atwood:

This letter corrects our substantially equivalent letter of February 22, 2006.

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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

Appendix 5 - Revised

Statement of Indication for Use

510(k) Number: K060113

Device Name: Dermacyn™ Wound Care

Indications for Use:

Dermacyn™ is intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

Prescription Use _____ OR Over-The Counter Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060113