K041161

MAY - 3 2005

510(k) Summary of the Dermacyn™ Wound Dressing

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	Zachary Woodson QA/RA Manager Tel: (707) 782-0792 Fax: (707) 782-0705 E-mail: zwoodson@oculusis.com
Date Prepared	February 1st, 2005
Trade Name	Dermacyn™ Wound Dressing
Common Name	Topical Solution
Classification Name	Solution, Wound Dressing
Predicate Device	Saljet Single Dose Sterile Saline Topical Solution, 0.9% w/v Sodium Chloride
Description	The subject device is an 8 ounce polyethylene bottle containing Dermacyn™ Wound Care Dressing intended for multi-use.
Indications for Use	For use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, abrasions and minor burns.
Substantial Equivalence	The product is similar in function and intended use to Saljet Single Dose Sterile Saline Topical Solution manufactured by Winchester Laboratories LL and includes among its labeled uses for moistening and lubricating absorbent wound dressing.
Non-clinical Performance	Non-clinical testing was conducted to confirm the safe and effective performance of Dermacyn™ Wound Care Dressing as compared to 0.9% sterile saline. Preclinical testing also demonstrated the biocompatibility of the subject device.
Conclusion	The Dermacyn™ Wound Care Dressing is substantially equivalent to the currently cleared and marketed Saljet Single Dose Sterile Saline Topical Solution, 0.9% w/v Sodium Chloride.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Mr. Zachary J. Woodson
QA/RA Manager
Oculus Innovative Science, Inc.
1129 North McDowell Boulevard
Petaluma, CA 94954

Re: K041161
Trade Name: Dermacyn™ Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 1, 2005
Received: February 2, 2005

Dear Mr. Woodson:

This letter corrects our substantially equivalent letter of May 3, 2005.

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 (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); 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 continue 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/dsma/dsmamain.html

Sincerely yours,

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

K041161

Indications for Use

510(k) Number (if known): K041161

Device Name: Dermacyn™ Wound Dressing

Indications for Use: Dermacyn™ Wound Dressing is intended for use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, abrasions and minor burns.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (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)

Division of General, Restor...

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