DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Combination Products
15800 Crabbs Branch Way
Suite 200, HFG-3
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

February 3, 2005

Oculus Innovative Sciences, Inc.
Attn: Zachary Woodson
QA/RA Manager
1129 N. McDowell Blvd.
Petaluma, CA 94954

Re: Request for Designation
Dermacyn™ Wound [ ]
Our file: RFD 2004.066
Dated: December 22, 2004
Received and Filed: December 27, 2004

Dear Mr. Woodson:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for Dermacyn™ Wound [ ] you submitted on behalf of Oculus Innovative Sciences, Inc. on December 22, 2004, and supplemented on January 10, 2004. The Office of Combination Products received and filed the RFD on December 27, 2004. As explained below, we conclude that Dermacyn™ Wound [ ] a device that will be reviewed and regulated by the Center for Devices and Radiological Health (CDRH) under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Description of the Product

According to the RFD, Dermacyn™ Wound [ ] a [ ] water product supplied in a plastic bottle [ ] that provides [ ] The RFD states that Dermacyn™ Wound Care is [ ] water. [ ]

Dermacyn™ Wound Care is intended for cleansing, debriding and removing foreign material from 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, and minor irritations of the skin. Oculus Innovative Sciences [1]

[1] [ ]

[redacted]

The RFD states that Dermacyn™ Wound [redacted] achieves its therapeutic effect by mechanical action. According to the RFD, the cleansing and debriding action of the product is solely due to the mechanical forces of the solution when [redacted] on the wound. The RFD acknowledges that Dermacyn™ Wound [redacted]. For these reasons, the RFD recommends that Dermacyn™ Wound [redacted] be classified as a device to be reviewed and regulated by CDRH.

Product Classification: Device

We have considered the information in the RFD and discussed the issues with staff in CDER and CDRH. We conclude that Dermacyn™ Wound [redacted] achieves its primary intended purposes of cleansing, debriding and removing foreign material from acute and chronic dermal lesions through the physical force of the solution [redacted] on the wound. [2] Therefore, we conclude that Dermacyn™ Wound [redacted] meets the definition of a device in that it is intended for use in the cure, mitigation, treatment, or prevention of disease in man, and it does not achieve its primary intended purposes through chemical or metabolic action within or on the body of man.[3] Accordingly, we conclude that Dermacyn™ Wound [redacted] is appropriately regulated by CDRH under the device provisions of the Act.

CDRH's Plastic and Reconstructive Surgery Devices Branch will be responsible for the product's premarket review and regulation. CDRH will consult with CDER as appropriate in its review of the product. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Mr. Stephen Rhodes, Chief, Plastic & Reconstructive Surgery Devices Branch, 301-594-3090 x131. Please include a copy of this letter with your initial submission to CDRH.

[redacted]

[2] As noted in the RFD, this determination is also supported by the Agency for Healthcare Research and Quality's Clinical Practice Guideline on Treatment of Pressure Ulcers. The guideline indicates that sufficient irrigation pressure is needed for adequate wound cleansing, and that appropriately pressurized wound irrigation may also be used for debridement. The RFD states that [redacted]

[redacted]

[3] Section 201(h) of the Act; 21 U.S.C. § 321(h). If the indication of the product changes, for example, to include a [redacted] claim, this classification as a device would not apply. In the event of such a change, a separate determination of the product's classification as a drug or device would be required.

You may request reconsideration of the classification of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact me at 301-427-1934.

Sincerely,

Suzanne O'Shea
Product Classification Officer

cc: Stephen Rhodes