DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

April 11, 2007

[redacted]
Quick-Med Technologies, Inc.
3427 SW 42nd Way
Gainesville, FL 32608

Re: Request for Designation
QMT NIMBUS Barrier Gauze Dressing[1]
Our file: RFD070011
Dated: February 19, 2007
Received and Filed: February 20, 2007

Dear [redacted]:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the QMT NIMBUS Barrier Gauze Dressing that you submitted on behalf of Quick-Med Technologies, Inc. on February 19, 2007. The Office of Combination Products (OCP) received and filed the RFD on February 20, 2007. As explained below, we conclude that the QMT NIMBUS Barrier Gauze Dressing is a device that will be reviewed by the Center for 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, the Nimbus dressing is intended as a single use primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. The RFD explains that it is a prescription dressing that should be changed as required, at least every 24 hours. The RFD states that the product is a cotton based cellulosic treated with poly(diallyldimethyl ammonium chloride) ("pDADMAC") that imparts a strong positive charge, so as to render the surface of the gauze bactericidal. According to the RFD, the pDADMAC is permanently bonded to, and non-leachable from, the gauze surface. As a result, the RFD explains, it "exerts its antimicrobial influence only within the dressing." Indeed, according to the RFD, the pDADMAC's "only intended purpose…is to control microorganisms in the dressing."

You recommend that the QMT NIMBUS Barrier Gauze Dressing be classified as a device and assigned to CDRH because you believe it has a device mode of action.

[1] The RFD states that the name of the product [redacted] However, in an email exchange with OCP on April 5, 2007, you stated that you wish to amend the RFD to remove the word [redacted] from the product's name. Consequently, our jurisdictional determination is for the product named "QMT NIMBUS Barrier Gauze Dressing."

Product Classification: Device

We have considered the information you provided in the RFD, as well as in our teleconference on April 4, 2007 and in your email of April 5, 2007, and we have discussed the issues with staff in CDRH, the Center for Drug Evaluation and Research, and the Office of General Counsel. We have determined that the QMT NIMBUS Barrier Gauze Dressing meets the definition of a device because 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.[2]

Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the Act. Any clinical investigations of the product are subject to the investigational device exemption (IDE) requirements found at 21 CFR 812 and should be conducted in conformity with those regulations. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Mr. David Krause, Acting Chief, Plastic and Reconstructive Surgery Devices Branch, at 240-276-3621. Please include a copy of this letter with your initial submission to CDRH. If you have any other questions about this letter, please contact Leigh Hayes at (301) 427-1934.

Sincerely,

Joanne R. Less, Ph.D.
Acting Director
Office of Combination Products

cc: David Krause

[2] We note that the jurisdictional classification of this product applies only to its description and intended use as set forth in this RFD. If you wish to make any new claims or redesign the product, such as a change that would provide for antimicrobial effect on the body, a separate jurisdictional determination will be necessary. As discussed in the April 4, 2007 teleconference, you stated that the Nimbus dressing's name will likely change because it is Quick-Med's intent to sell the product to another manufacturer, if it receives marketing approval or clearance from FDA. If the agency finds that the pDADMAC component may be acting as a drug rather than a device, a separate jurisdictional determination may be necessary.