DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quick-Med Technologies, Inc
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 25 2009

Regulation Number: 21 CFR 878.4015
Classification: Class II
Product Code: NYS

Re: K060662 Evaluation of Automatic Class III Designation
QMT NIMBUS Barrier Gauze Dressing

Dear Ms. McNamara-Cullinane:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the QMT NIMBUS Barrier Gauze Dressing intended for use as primary dressing for exuding wounds, first and second degree burns, surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the QMT NIMBUS Barrier Gauze Dressing, and substantially equivalent devices of this generic type into class II under the generic name, Wound Dressing with Poly(diallyl dimethyl ammonium chloride)(pDADMAC).

FDA identifies this generic type of device as:

> "A wound dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) additive is a device that is a sterile barrier wound dressing intended for use as a 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 device consists of a textile substrate and permanently bound pDADMAC. The device acts as a physical barrier to outside contaminants and does not act on the surface or interior of the wound nor does it contain antimicrobial agents that act on the body."

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency

determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 07 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device type under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device type. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On May 10, 2007, FDA filed your petition requesting classification of the QMT NIMBUS Barrier Gauze Dressing into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on June 23, 2006 automatically classifying the QMT NIMBUS Barrier Gauze Dressing in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. After our June 23, 2006, letter classifying this device into class III, you submitted an appeal of our decision under the regulations found in 21 CFR 10.75. Following our response to your appeal from Director, Office of Device Evaluation, you submitted a Request for Designation under 21 CFR Part 3. On April 11, 2007, the Office of Combination Products sent you a letter stating you were a device to be review by the Center for Devices and Radiological Health. In order to classify the QMT NIMBUS Barrier Gauze Dressing into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition FDA has determined that the QMT NIMBUS Barrier Gauze Dressing intended for use as primary dressing for exuding wounds, first and second degree burns, surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the Act, the QMT NIMBUS Barrier Gauze Dressing is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC)," to address the specific risks to health associated with a wound dressing with poly(diallyl dimethyl ammonium chloride) (pDADMAC). The risks identified in the Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) are: infection, adverse tissue reaction, leaching of the additive, pDADMAC into the wound, degradation of materials leading to device failure, necrosis and pain.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the wound dressing with poly(diallyl dimethyl ammonium chloride) (pDADMAC) they intend to market and receive clearance, prior to marketing their device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Sam Arepalli, Ph.D., at (240) 276-3626.

Sincerely yours,

Christy Foreman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health