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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

April 21, 2003

WARNING LETTER NYK 2003-23

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Edward D. Breen  
Chairman and Chief Executive Officer  
Tyco International, Inc.  
273 Corporate Drive, Suite 100  
Portsmouth, NH 03801

Dear Mr. Breen:

During an inspection of your establishment, Tyco Healthcare/Kendall Division, located at 453 County Route 45, Argyle, New York, on January 28 – February 5, 2003, our investigator determined that your establishment manufactures 3.7 Fr Polyurethane Umbilical Vessel Catheters. These catheters are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain an adequate design change procedure as required by 21 CFR 820.30(i). For example, Manufacturing Notification procedures were not followed for the validation or verification of design changes before their implementation for the 3.7 Fr line extension of the umbilical vessel catheter (P/N 8888-160350) with labeling compatibility with a multiparameter sensor from [REDACTED]. Also, your firm failed to conduct design change verification or validation under actual or simulated conditions using post sterile production lots at worst case using extruded blanks with a minimum tube internal diameter of [REDACTED] inches.

Your firm's February 20, 2003 written response to this observation is inadequate.

2. Failure to adequately establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example, seven of the [REDACTED] lots of 3.7 Fr Polyurethane Umbilical Vessel Catheters (P/N 8888-160350) released were not subject to post sterile finished device acceptance prior to distribution.

Your firm's February 20, 2003 written response to this observation is inadequate.

As noted, we received and reviewed your February 20, 2003 written response to the FDA 483 covering the period January 28 – February 5, 2003. We have determined your response fails to satisfactorily address the above two deficiencies. However, your firm's February 20, 2003 written response to the following observation is adequate: Failure to adequately monitor and control process parameters and component and device characteristics during production, as required by 21 CFR 820.70(a)(2). For example, urethane umbilical vessel catheters, specifically the 2.5 and 3.7 Fr, require [REDACTED]

[REDACTED] It was not recorded in the production record the actual start and stop time to document that the catheters were [REDACTED]. We also acknowledge your firm voluntarily recalled all lots of these catheters due to complaints that report the lumen of the catheter may not accommodate the designated sensor promoted with the product.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective, and preventive action on your Quality System.

We are aware violations of the Medical Device Quality Systems Regulations at a facility operated by the Valley Labs Division of Tyco Healthcare, Radionics, Inc., 22 Terry Avenue, Burlington, MA, were brought to your attention in Warning Letter NWE-14-02W. Warning Letter NWE-14-02W, addressed to Mr. L. Dennis Kozlowski, Chairman of the Board & Chief Executive Officer, Tyco International, Ltd., One Tyco Park, Exeter, NH, was issued by our New England District Office on March 8, 2002. You should be aware that future violations of the Act at any other Tyco Healthcare division or facility may result in the initiation of regulatory action by FDA.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

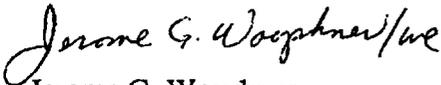
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Tyco International, Inc.  
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Your response should be sent to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202 (telephone 716-551-4461, ext. 3168).

Sincerely yours,

  
Jerome G. Woysner  
District Director

Enclosure: Form FDA 483 dated 1/28-2/5/03

cc: Richard J. Meelia  
President & CEO  
Tyco Healthcare  
15 Hampshire Street  
Mansfield, MA 02048

cc: David Olson  
Vice President, Regulatory Affairs  
Tyco Healthcare/Kendall  
15 Hampshire Street  
Mansfield, MA 02048

cc: William H. Bunn  
Plant Manager  
Tyco Healthcare/Kendall  
453 County Route 45  
Argyle, NY 12809