DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

December 12, 2013

Mr. Javed
Partner
Frix Surgical
P.O. Box #950, College Road
Sialkot - Pakistan

FEI: 3010509308

and

Mr. Faizan Riaz
Auditor
QMS Certification International
Muzzafer Pur, Opp. Masjid Shah-e-Khorasan
Roras Road
Sialkot, Pakistan

Dear Messrs. Javed and Riaz:

This is to acknowledge receipt of the November 4, 2013 letter from Mr. Faizan Riaz certifying the compliance of Frix Surgical with the Food and Drug Administration (FDA) Quality System Regulation of 1997, which includes the current good manufacturing practice (CGMP) requirements. The Quality System Regulation is set forth in Title 21, Code of Federal Regulations (CFR), Part 820. The consultant certification confirmed that a quality system audit of Frix Surgical was performed October 11, 2013, and a corrective action plan was implemented and verified on October 24, 2013.

The quality system audit report states that Frix Surgical manufactures surgical instruments. Based on the consultant certification, Frix Surgical has been placed on the Green List of Import Alert #76-01 (Importation of Medical Instruments from Pakistan), http://www.accessdata.fda.gov/cms_ia/importalert_224.html. You may begin exporting devices to the United States (U.S.) that were manufactured after the consultant certified your firm's compliance with the CGMP's; however, your shipments are subject to the guidance outlined in the revised Import Alert #76-01.

The FDA may periodically detain and sample devices from your firm for verification of conformance to the Quality System Regulation. Failure of the sample will result in your firm being removed from the Import Alert until your firm is re-inspected and documentation is submitted to the FDA to show compliance with the Quality System Regulation.

Your placement on the Import Alert is limited to devices manufactured under the name of Frix Surgical, P.O. Box #950, College Road, Sialkot - Pakistan. In the event the manufacturing name and/or address change, FDA requests that notification be immediately forwarded to this office. A change in the name and/or address of the manufacturing facility without notifying FDA will result in a re-evaluation of the compliance status of your firm.

The decision based on your consultant certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan for an inspection of your facility. During this inspection all corrections and procedures will be evaluated and confirmed. Any new CGMP deviations, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of your firm, Frix Surgical, including the possibility of removal from the import alert. You will be advised of the timing of FDA's inspection schedule.

If you have not conducted a Quality System audit in the past two years, we request that you conduct a Quality System audit within 6 months of receiving this letter. A copy of your most recent audit should be submitted to FDA for review. Frix Surgical has a responsibility to conduct periodic Quality System audits to ensure conformance with the Quality System regulation.

The audit report should address, at a minimum, the applicable elements of the Quality System Regulation including the following information, as appropriate. This should not be considered an all inclusive list and additional information may be included.

Current Audit Summary and Follow-up Recommendations

Quality System Review Elements:

Quality Manual
Corrective Action Plan
Device Master Record
Device History Record
Calibration
Internal Audits
External Audits
Facilities
Supplier Control
Specifications
Production Equipment
Cleaning and Sanitation
Personal Hygiene
Training
Hazardous Materials Handling
Receiving, Storage, and Shipping
Traceability and Recall
Consumer Complaints/MDRs
Pest Control

All manufacturers exporting surgical instruments to the United States should use stainless steel meeting the latest version of the Standard Specification for Wrought Stainless Steels for Surgical Instruments, ASTM standard F-899-11. Please assure your documents and requirements conform to ASTM standard F-899-11.

Establishments that are involved in the production and distribution of medical devices intended for use in the United States are required to register and list the devices annually with the FDA. This registration and listing process may be completed electronically. For more information and to complete the process please go to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

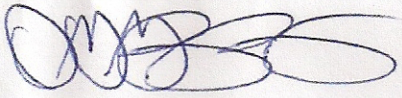
All correspondence should be addressed to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
Attention: Branch Chief
White Oak Building 66, Room 2622
10903 New Hampshire Avenue
Silver Spring, MD 20993 USA

Please reference your Facility Establishment Number (FEI), 3010509308, in future correspondence and in the registration process.

If you have any questions regarding this correspondence, or need further assistance, please contact J. Girard Griggs at john.griggs@fda.hhs.gov or (301) 796-5589.

Sincerely yours,



for Carole Jones
Chief
Imports Branch
Division of International Compliance and Operations
Office of Compliance
Center for Devices and Radiological Health