



September 6, 2017

Mr. Farhan
Chief Executive Officer
Surgi Valley
12c Small Industrial Estate, Shahab Pura
Sialkot - Pakistan

FEI: 3013035234

and

Mr. Hassan Ali
Auditor
Dynamex Certification Services
Iqbal Town Defence Road, New HBL Bank
Sialkot, Pakistan

Dear Messrs. Farhan and Ali:

This is to acknowledge receipt of the July 19, 2017 letter from Mr. Hassan Ali (Auditor) certifying the compliance of Surgi Valley (Firm) with the United States 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 quality system audit report provided by the Auditor states that Surgi Valley manufactures surgical instruments and that a quality system audit was performed on June 29-30, 2017. The inspection found deficiencies and the Auditor states that a corrective action plan was implemented on July 15, 2017. The Auditor recommends that the Firm be added to the Green List of Import Alert 76-01, "Exempt from Detention Without Physical Examination of medical instruments from Pakistan."

FDA has reviewed the audit report of Surgi Valley, including the Quality System Manual, Test Data, and the Corrective Action Plan submitted.

Based on our review, Surgi Valley will be placed on the Green List of Import Alert 76-01. The firm may begin exporting devices to the United States that were manufactured after the consultant certified the Firm's compliance with the cGMP's; however, the Firm's shipments are subject to the guidance outlined in the revised Import Alert 76-01.

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

The Firm's placement on the Green List of Import Alert 76-01 is limited to devices manufactured under the name of Surgi Valley, 12c Small Industrial Estate, Shahab Pura, Sialkot - Pakistan. In the event the Firm's 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 Firm's manufacturing facility without notifying FDA will result in a re-evaluation of the compliance status of the Firm.

The decision based on the Auditor's certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan for an inspection of the Firm. 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 the Firm, Surgi Valley, including the possibility of removal from the Green List of Import Alert 76-01. You will be advised of the timing of FDA's inspection schedule.

If the Firm has not conducted a Quality System audit in the past two years, we request that a Quality System audit be conducted within 6 months of receiving this letter. A copy of the Firm's most recent audit should be submitted to FDA for review. Surgi Valley 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-899-12. Please assure that the Firm's documents and requirements conform to ASTM standard F-899-12.

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>.

Electronic submission documents should be emailed to cdrhocpakistanaudit@fda.hhs.gov. Paper submission documents and 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 3540
10903 New Hampshire Avenue
Silver Spring, MD 20993 USA

Please reference your Facility Establishment Number (FEI), 3013035234, 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,



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