August 24, 2023

Mr. Usman Akram
Chief Executive Officer
Surgitronix Instruments (Private) Limited
Building #349 Block A, Jubilee Town Canal Road,
Lahore, Pakistan

&

Mr. Shahzad Shoukat
Auditor
DCS
Iqbal Town Defence Road, New HBL Bank,
Sialkot, 51310, Pakistan

Dear Mr. Akram and Mr. Shoukat:

This is to acknowledge receipt of the April 29, 2023, letter from Mr. Shahzad Shoukat (Auditor) certifying the compliance of Surgitronix Instruments (Private) Limited 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 Surgitronix Instruments (Private) Ltd manufactures medical device instruments and that a quality system audit was performed on April 10-11th, 2023. The inspection found three marginal observations and the Auditor states that a corrective action plan was implemented on April 27th, 2023. The Auditor recommends that the firm be added to the Green List of Import Alert 76-01, "Detention Without Physical Examination of Medical Instruments from Pakistan."

FDA has reviewed the audit report of Surgitronix Instruments (Private) Limited including the Quality System Manual, Test Data, and the Corrective Action Plan submitted.

Based on our review, Surgitronix Instruments (Private) Limited 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 Green List of Import Alert 76-01 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 medical instrument devices manufactured under the name of Surgitronix Instruments (Private) Limited located at Building #349 Block A, Jubilee Town Canal Road Lahore, Pakistan. In the event the firm's name and/or manufacturing facility 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 that FDA is able to visit the firm for an inspection of the manufacturing 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 the firm, 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. The firm 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
- Audit Follow-up Recommendations
- Corrective Action Plan
- Device Master Record
- Device History Record
- Material Analysis
- Material Hardness Tests
- Material Corrosion Tests
- Quality Manual
- Calibration
- Internal Audits
- External Audits
- Facilities
- Supplier Control
- Specifications
- Production Equipment
- Cleaning and Sanitation
- Personal Hygiene
- Training
- Hazardous Materials Handling
- Receiving, Storage, 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 F899-12b. Please assure that the Firm's documents and requirements conform to ASTM standard F899-12b.

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**.

Cover letters contained in the electronic submission should be addressed to:

Mrs. Deniz B. Mackey, BME, M.S., B.S.
Assistant Director
Imports & Registration and Listing Team
U.S. Food and Drug Administration - CDRH
Office of Regulatory Programs
Division of Regulatory Programs 2
White Oak Building 66
10903 New Hampshire Avenue
Silver Spring, Maryland 20993 USA

Please reference your Facility Establishment Inspection (FEI) Number 3027658059 and in future correspondence and in the registration process.

If you have any questions regarding this correspondence or need further assistance, please contact Lisa M. King at lisam.king@fda.hhs.gov or (301) 796-5785.

Sincerely yours,

Deniz Mackey -S

Digitally signed by Deniz Mackey -S
Date: 2023.09.01 11:19:53 -04'00'

Deniz B. Mackey
Assistant Director
Imports and Registration & Listing Team
Division of Regulatory Programs 2
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health