



Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd
Rockville, MD 20850

APR 1 2009

Mr. Touqir Ahmed
Chief Executive
M/s SIMRIX Surgical Co.
Head Marala Road, Chowk Gohadpur
Jamil Plaza
Sialkot - Pakistan

and

Mr. Mohammad Ashraf
Auditor
Quality Management Consultant
Khadim Ali Road, Kotli Behram
Sialkot, Pakistan

Dear Messrs. Ahmed and Ashraf:

This is to acknowledge receipt of an August 19, 2008, letter from Mr. Mohammad Ashraf certifying the compliance of SIMRIX Surgical Co. 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 SIMRIX Surgical Co. was performed August 9, 2008, and a corrective action plan was implemented and verified on August 18, 2008.

The quality system audit report states that SIMRIX Surgical Co. manufactures surgical instruments. Based on our review of the audit results and certification, SIMRIX Surgical Co. has been placed on Attachment A of Import Alert #76-01 (Detention without Physical Examination of Surgical Instruments). 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 may be subject to the guidance outlined in Attachment A of Import Alert #76-01. After five consecutive shipments comply with the import alert guidance, you may request your firm be placed on Attachment B. Submit your request directly to the FDA district office for their concurrence and further submission to this office for action.

The placement of the firm on Attachment A is limited to devices manufactured under the name of SIMRIX Surgical Co., Head Marala Road, Chowk Gohadpur, Jamil Plaza, 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