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, SIMRIX Surgical Co., including the possibility of removal from Attachment A.

We request that a quality system follow up audit be performed at SIMRIX Surgical Co. within six months of exporting devices to the U.S. You will be advised of the timing of FDA's inspection schedule.

SIMRIX Surgical Co. has an ongoing responsibility to conduct internal self-audits to assure you continue to maintain conformance with the Quality System Regulation.

If you have any questions regarding this correspondence, or need further assistance, please contact Alan C. Gion at (240) 276-0115 or FAX (240) 276-0114.

Sincerely yours,

Thomas C. Knott
Chief
General Surgery Devices Branch
Division of Enforcement A
Office of Compliance
Center for Devices and
Radiological Health