DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 2007

Mr. Ahmed Sheraz
CEO
Emerald Instruments
Roras Road
P.O. Box 766
Sialkot - Pakistan

and

Mr. M. Ejaz Ghumman
Auditor
QA International
First Floor Shahab Center
Opp Small Industrial Estate
P.O. Box 3000

Dear Messrs. Sheraz and Ghumman:

This is to acknowledge receipt of an October 3, 2006, letter from Mr. M. Ejaz Ghumman certifying the compliance of Emerald Instruments 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 Emerald Instruments was performed August 4-5, 2006, and a corrective action plan was implemented and verified on August 27, 2006.

The quality system audit report states that Emerald Instruments manufactures surgical instruments. Based on our review of the audit results and certification, Emerald Instruments 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 Emerald Instruments, Roras Road, P.O. Box 766, 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, Emerald Instruments, including the possibility of removal from Attachment A.

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

Emerald Instruments 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 Brenda Pope 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