DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 28 2005

Mr. Junid Ameen
Managing Director
Weldon Instruments
62/24 Ghazi Road
Cantt - Sialkot
Pakistan

and

Mr. Shakeel Baig
Chief Executive
International Quality Systems Consultants
Talwara Mughlan
Sialkot-Pakistan

Dear Mr. Ameen and Mr. Baig:

This is to acknowledge receipt of a September 15, 2005, letter from Mr. Shakeel Baig certifying the compliance of Weldon 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 quality system audit report states that Weldon Instruments manufactures surgical stainless steel instruments. Based on our review of the audit results and certification, Weldon 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 CGMPs. 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 Weldon Instruments, 62/24 Ghazi Road, Cantt-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 FDA is assured by both the consultant and Weldon Instruments that no devices will be imported into the U.S. that is not specifically manufactured by Weldon Instruments. This includes other manufacturers in Pakistan completing specific manufacturing processes for Weldon Instruments, and other manufacturers in Pakistan providing their devices to Weldon Instruments for importation into the U.S.

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 Weldon Instruments, including the possibility of removal from Attachment A.

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

Weldon 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 me at (240) 276-0115 or FAX (240) 276-0114.

Sincerely yours,

for

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