DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mian Faisal
Chief Exective Officer
Beauty Teck International
Air Port Road Gohad Pur,
Sialkot-Pakistan.

and

Mr. M. Ejaz Ghumman
Auditor
QA International Pakistan (North)
P.O. Box 3000
First Floor, Shahab Center Opp Small Industrial Estate
Sialkot, Pakistan

Dear Messrs. Main and Ghumman:

This is to aknowledge receipt of a October 15, 2006, letter from Mr. M. Ejaz Ghumman certifying the complience of Beauty Tech International 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 est forth in Title 21, Code of fedral Regulations (CER), Part 820. The consultant certification confirmed that a quality system audit of Beauty Tech International was performed October 06-07, 2006, and a corrective action plan was implemented and verified on May 14, 2006.

The quality system audit report states that Beauty Tech International manufactures surgical instruments. Based on our review of the audit results and certification, Beauty Tech International has been placed on Attached A of Import Alert #76-01 (Detention without Physical Examination of surgical Instruments). You may being exporting devices to the United States (U.S.) that where manufactured after the consultant certified your firm's complience with the CGMP's: however, your shipment 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 Beauty Tech International, Air Port Road Gohad Pur, Sialkot - Pakistan.
In the evnt 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 complience status of your firm.

The dicision 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 complience status of your firm, Beauty Tech International, including the possibility of removal from Attachment A.

We request that a quality system follow up audit be performed at Oritech International within six months of exporting devices to the U.S. you will be advised of the timing of FDA's inpection schedule.

Beauty Tech International 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 Laura A. Adam at (240) 276-0115 or FAX (240) 276-0114.

Sincerly yours,

Thomas C. Knott
Chief
General Surgery Devices Branch
Division of Enforcement A
Office of Complience

Center for Devices and
Radiological Health