

Food & Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202-1097**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

July 7, 1998

**WARNING LETTER  
CIN-WL-98-321**Kevin Benoit, President  
Stille Beta Inc.  
530 S. Main St., Bldg. #17  
Akron, Ohio 44311

Dear Mr. Benoit:

During an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on June 2-12, 1998, our Investigators determined that your firm manufactures hydraulic stretchers and imaging tables with carbon fiber tops. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that your devices are adulterated within the meaning of Section 501(h) of the Act in that, the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to establish and implement an adequate complaint handling program.

Complaints that are received at your firm are not always recorded on your firm's Complaint Report/Response Forms and as a result there is no documentation that adequate follow-up information on complaints is received and reviewed. Completing the Complaint Report/Response Form (██████████) would provide valuable information such as whether FDA was notified (MDR event); the complaint was a safety event; patient information and details; details when the complaint was an equipment malfunction; information on management review and whether an investigation was needed; and whether corrective action was required, to include the CAR form number. Of ██████ complaints on record at your firm since 9/19/96, 65% were missing Complaint Report/Response Forms.

In addition, some of the Complaint Report/Response forms that were filled out for complaints received by your firm were incomplete. Some complaint reports did not indicate whether the complaint was safety related; some complaint reports did not indicate whether a failure investigation was needed; some complaint reports lacked the reason for not investigating and the name of the individual responsible for the decision not to investigate; and some complaint reports did not have a final review signature.

Failure to establish and implement adequate record keeping procedures.

The device master records (DMRs) are incomplete. For example, labeling/packaging specifications are not included in the DMRs for the devices you manufacture; changes to the DMRs do not contain a description of the changes, identification of the affected documents, and the signature of the approving individual and the approval/effective dates.

Failure to document, review, approve, and validate changes to product design.

Design changes were made to the following devices and the verification/validation of the design changes were not documented: the footboard on drawing part [REDACTED] for revisions B & D (Table 4008); the footboard on drawing part [REDACTED] for revisions B & C (Table 4008); design changes for the Eurodynamic table (4005) and design changes for the Agio-OR table (4150).

Failure to implement procedures for corrective and preventative action.

Although your firm has a Corrective Action Procedure ([REDACTED]), corrective action reports are not generated for revisions to work process and work instructions for retrofits and redesign. For example, corrective and preventative action was taken to correct a problem with the footboard for Table S4008. As a result of complaints in the field that the footboard for Table S4008 was bending as patients applied their body weight to the footboard, a change in the design of the footboard was made to make the material of the footboard rail thicker and able to withstand more weight. There is no documentation available for this change and no corrective action report was generated.

Failure to establish and implement adequate design control procedures.

There is no design transfer procedure currently in place. For example, the design of the Agio-OR table is currently at the design transfer stage and there is no procedure describing how the design transfer will occur and the approval process for transferring the design to manufacturing.

Risk analyses are not included in the design control procedure. For example, there is no documentation that risk analysis was done for the redesign of Table 4048 (Table 4150). Although it was stated by management at your firm that a risk analysis was conducted for the Agio-OR Table which was a redesign, there is no documentation that the risk analysis was performed.

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Failure to adequately control environmental conditions in order to assure that the manufacturing site does not have an adverse effect on a device's fitness for use.

No precautions are taken during the assembly of circuit boards to prevent electrostatic discharge (ESD). There are no procedures for controlling ESD and no precautions such as wrist traps or grounding pads are being used to control ESD.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

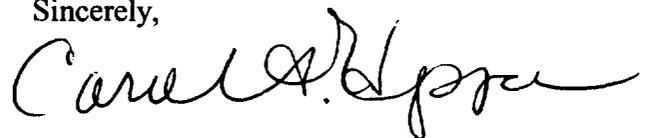
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,



Carol A. Heppe  
Acting District Director  
Cincinnati District