



October 8, 2004

**VIA FEDERAL EXPRESS**

Carl Severinghaus  
President & General Manager  
Tecan US  
4022 Stirrup Creek Road, Suite #310  
Durham, NC 27709

**Warning Letter**  
(05-ATL-01)

Dear Mr. Severinghaus:

During an inspection of your firm located at 4022 Stirrup Creek Road, Durham, NC on 5/10-27/04, our investigators determined that your firm is a manufacturer and distributor of the Tecan Clinical Workstation (TCW) which is made up of various components including the Tecan Genesis RSP. The Tecan Clinical Workstation is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C §321(h) because it is used for the purposes of performing in-vitro diagnostic tests on patient samples.

The above stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation for medical devices, as specified in Title 21 Code of Federal Regulations (21 CFR), Part 820. At the close of the inspection, you were issued a Form FDA 483 which delineated a number of significant QS inspectional observations, including, but not limited to, the following:

1. Failure to have complete validation of the [REDACTED] software program, as required by 21 CFR 820.30(g). Your firm did not have documentation of complete requirements specifications and software design specification for the entire [REDACTED] software program. Documentation of the software program provided by the original developer of the software was limited and did not show a complete validation of the software program. Additionally, validation of the software upgrades was limited to the changes or additions made to the software program by the upgrades. Validation has not been conducted on the entire [REDACTED] software program. Test cases only tested the software modifications with no references or linkage to an overall software program validation. (FDA 483 item #1)
2. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a)(4). Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device. Specifically, your firm implemented two corrective actions in response to potential patient sample mismatches occurring with the use of the Tecan Clinical Workstation with [REDACTED] software. These corrective actions included a manual workaround for patient sample

identification and new purging instructions. Your firm failed to verify or validate these corrective actions prior to implementation in the field. (FDA 483 item # 2& 13)

3. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). There were no overall design procedures. Your firm did not have any written design control procedures in place. Your firm did not have procedures for making or controlling software changes during the software development process. (FDA 483 item #3)
4. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of the QS regulation and your firm's established quality policy and objectives, as required by 21 CFR 820.20 (c). Specifically, your management reviews did not evaluate or address deficiencies in the firm's established management controls, design controls, and corrective and preventive action subsystems. Also, while your firm had corporate procedures for management reviews, these procedures were not implemented at Tecan US. Even though you indicated to our investigators that a management review took place in 2004, no documentation of that management review was available. Also, no prior management reviews have been held by Tecan US. (FDA 483 item # 4,6, &7).
5. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your quality audit procedures did not include the parts of the quality system that were to be audited. Moreover, even though your audit procedures specified that such internal audits were to be conducted annually, the last such internal audits were done in 2002 and 2000. These audits were conducted by the Quality Manager, who has direct responsibility for the areas being audited such as QA Organization, Equipment, Document Control and QA/QC procedures, in violation of 21 CFR 820.22. (FDA 483 item #5, 8, 9, &10)
6. Failure to evaluate complaints to determine whether the complaints represent an event which is required to be reported to FDA under Part 803, Medical Device Reporting, as required by 21 CFR 820.198(a)(3). For example, your firm indicated, and FDA's inspection revealed, that even though all service calls are considered complaints, service calls were not always evaluated to determine if the incidents are MDR reportable. Furthermore, your procedure for MDR reporting does not include a mechanism for determining when an event meets the criteria for MDR reporting. (FDA 483 item #12).
7. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your firm has not established a system for maintaining all complaint information in a complaint file. (FDA 483 item #16)

In addition, review of specific marketing literature collected during the inspection which is entitled, Viral RNA Extraction, Nucleic Acid Testing with the Tecan Genesis RSP, revealed that the exemptions from section 510(k) for your Tecan Genesis RSP are limited under 21 CFR 862.9(b) and (c)(3). This marketing literature indicates that the device can identify Hepatitis A, C, E and G, HIV, and HTLV, which is beyond the scope of its current Class 1, 510(k) exemption status and thus would require a 510(k) for such claims. You should contact the Office of In-vitro Diagnostic Devices in the Center for Devices and Radiological Health at 301-594-1243 to discuss the exemption status and submission of a

510(k) for this device. You should also perform a comprehensive review of your other products to determine the need for 510(k) submission.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

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. Additionally, FDA will not approve any applications for premarket approval (PMAs) for Class III devices to which the Quality System regulation deficiencies are reasonably related until the violations have been corrected. Also, no request for Certificates For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, actions for seizure, injunctions, and/or civil money penalties

Please provide this office in writing within fifteen (15) working days of receipt of this letter a report of the specific steps you have taken, or will take, to identify and correct the noted violations, including an explanation of each step being taken to ensure that similar violations will not recur. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and time within which the corrections will be completed.

We acknowledge receipt of your letters dated May 28, 2004, June 14, 2004, June 29, 2004, July 26, 2004, and August 31, 2004 which were in response to the FDA 483. Your responses are currently being reviewed and will be addressed in a separate letter. We also acknowledge that you indicated in your June 29, 2004 letter that relevant software, engineering, manufacturing, integration and assembly personnel will be transferred to your sister facility, Tecan Systems, in San Jose, CA. You may refer to your responses in your answer to this Warning Letter. Please send your response to the attention of Serene N. Ackall, Compliance Officer at the address noted in the letterhead. If you have any questions about this letter, you can contact Serene Ackall at 404-253-1296.

Sincerely,



Mary Woleske, Director  
Atlanta District

Cc: Mr. Steve Levers, President  
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San Jose, CA 95131