



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-53

April 28, 1997

James M. Shepherd, Jr.
President/CEO
Statcorp, Inc.
7037 Commonwealth Ave., Suite 8B
Jacksonville, Florida 32220

Dear Mr. Shepherd:

We are writing to you because on March 19, 27 and April 3-4, 1997, FDA Investigator H. Randy Bringger, collected information that revealed serious regulatory problems involving a product identified as the Unifusor I blood/fluid infusion cuff, which is made and marketed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your 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 the manufacture, packing, storage, or installation are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to maintain an adequate Device Master Record (DMR) for the device, e.g., there is no prepared, dated, and signed DMR for the Unifusor I pressure infusion cuff including, but not limited to, component and finished device testing.
- Failure to establish, implement and maintain an adequate change control procedure to assure formal approval prior to implementation, e.g., undocumented decrease in sampling rate for the "bullet" testing of the incoming Unifusor I cuff component; lack of documentation disposing of Unifusor I finished device inspection rejects, and the sleeve fabric component change itself.

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- Failure to review, approve, implement, validate and document changes to the DMR, e.g., the Unifusor I sleeve material component change was not validated.
- Failure to adequately investigate the failure of a device to meet its performance specifications after a device has been released for distribution, and to document the investigation including conclusions and follow-up. There were no records available documenting all of the failure investigation activities covering the Unifusor I sleeve component.
- Failure to review, evaluate, investigate, and document any complaint pertaining to injury, death, or hazard to safety for the Unifusor I, e.g., there were no records documenting the investigation conducted to obtain information necessary to determine the root cause of a failure involving a Unifusor I cuff losing pressure resulting in a clotted needle to an arterial line.
- Failure to establish adequate production controls to assure conformance to specifications, e.g., there are no specified limits identified for the Unifusor I for which you will take action when failures/defects are discovered.

The inspection also revealed that your device is misbranded within the meaning of section 502(t)(1) in that there are failures to comply with any requirements prescribed under section 518 respecting the device.

- Failure to establish adequate Medical Device Report (MDR) procedures, e.g., there is no standard review process for determining when a complaint or event meets the criteria for reporting as a MDR, or there is no requirement for documenting deliberations and justifications of decisions in determining if an event is reportable.

You should know that these violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against your further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

We have reviewed your written response dated April 16, 1997 and have the following comments:

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FDA 483 Item #1: Your response is inadequate because you fail to state what procedures you have implemented to conduct investigations and analyses of complaints. Your response also fails to provide a copy of these new procedures for our review. The documentation you provided was the same as what was collected by the investigator during the inspection. Your response also fails to address complaint #96-011, i.e., you failed to document any follow-up investigation including telephone calls or other communications, any evaluations made, and your firm's conclusions of the root cause of the reported incident.

FDA 483, Item #2: Your response is inadequate because it fails to discuss or provide a copy of the new procedure which you have implemented to correct the observation.

FDA 483, Item #3: Your response is inadequate because it states that the DMR in question is on file. It was not available during the inspection and a copy of the document was not provided with the response. Please provide a copy for our review.

FDA 483, Items #4, 5, 6 & 8: Your responses are inadequate because you failed to provide copies of new policies and procedures you state have been implemented for change control, validation, testing, and failure investigations. We are not able to assess the extent and quality of these corrections unless a copy of these documents is provided for our review.

FDA 483, Item #7 & 9: Your responses appear to be adequate in light of other corrections promised. Please ensure that all training conducted and completed is adequately documented for all employees in each of their personnel folders. This documentation may be requested for review by a FDA investigator.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices.

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This letter pertains only to the issue of good manufacturing practices for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the GMPs or other FDA requirements affecting your particular device, or about the content of this letter, please feel free to contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely yours,



Douglas D. Tolen
Director, Florida District