DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

N 1953N

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-62

July 16, 1998

Joseph B. Gross, President
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 34643

Dear Mr. Gross:

We are writing to you because on May 18-22, 26-29 and June 2, 1998, FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the Apex Irrigation pump and the Mini-Revo, implantable screw (Class II) which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to 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) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the 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 the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish, maintain, and document complaint system procedures including the timely review and evaluation of complaints, e.g., numerous complaints received and documented in your firm's service records were not evaluated and documented as complaints or some were not evaluated for several months after receipt (FDA 483, Item #2 & #3).

Your response dated June 17, 1998 to FDA 483, Item #1 is inadequate because it fails to provide copies of changes made to SOP 13104 addressing the observations. The response also states that four (4) devices were returned by the complainant, and were evaluated. There are no records provided showing the evaluations conducted and the conclusions determined from the evaluations. The response fails to include the records that were found to be incomplete and have since been corrected and no documentation was provided covering the training given, e.g., who conducted the training, on what dates, who received the training, and what the training consisted of.

- Failure to establish and implement written procedures to control the reprocessing of devices or components to assure the reprocessed device or component meets its original specifications, e.g., power supplies were reprocessed without following approved written procedures or documented quality assurance testing. In some cases devices were found not to have passed finished product testing but were released and used to manufacture a finished device (FDA 483, Item #6).

Your response dated June 17, 1998 to FDA 483, Item #6 is inadequate because it fails to provide the procedures that you state are already in place, any updates to the procedures and documentation of product that has been reprocessed. Your response also fails to provide documentation of training provided.

- Failure to establish and implement procedures adequate to control nonconforming vendor supplied components, e.g., a minimum of three lots of a power supply were found to fail incoming component specifications or failed after installation in a device. No failure investigation was documented.

Your response dated June 17, 1998 appears to be adequate to address the listed observation. Please provide copies of all documentation of the corrective actions that you make addressing this observation for our review and file once completed.

The inspection revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act, in that you failed to furnish any material or information required by or under section 519 respecting the devices as follows:

- Failure to adequately investigate complaints and to report all required information, e.g., records reviewed did not show that devices involved in MDR #1017294-1998-00010 were returned for evaluation and that an appropriate investigation into the root cause of the device malfunction was conducted and reported, and

- Failure to evaluate related devices or lots of device to determine the extent of the reported complaint.

Your response dated June 17, 1998 appears to be adequate to address this observation.

We also note that during the inspection FDA 483, Items #9 & #12 were corrected and verified and that corrective actions to FDA 483, Item #4 were made but not verified. The annotated copy of the FDA 483 (Inspectional Observations) states that you will complete all corrective actions by September 2, 1998.

You should know that these are serious violations of the law that 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 further marketing of the product, or assessing civil money penalties. 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 Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. 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.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter the corrective actions you intend to take to the items that were noted above to be inadequate. Also, please advise, if there are any other steps you are taking to prevent this from happening again, in addition to those corrective actions previously noted in your June 17, 1998 letter. We note that you have promised correction to all noted violations by September 2, 1998. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Orlando, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality

System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District