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Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**VIA FEDERAL EXPRESS**

Ref: Customs Entry No.: 606-0063471-5/001/001  
Product: Ultrasound Measuring Device (Model DMS-101)  
2 Units

**WARNING LETTER****FLA-01-44**

March 19, 2001

Mr. Fernando Guevara  
Danatech Medical Systems, Inc.  
8100 S.W. 81<sup>st</sup> Drive  
#202  
Miami, Florida 33143

Dear Mr. Guevara:

The Food and Drug Administration (FDA) attempted to examine a shipment of ultrasound measuring devices offered for entry into the United States by your firm on March 1, 2001, under the above referenced entry number. The FDA inspectors observed that two of the devices in the entry were not available for examination. Title 21, Code of Federal Regulations (21CFR), Section 1.90 requires the importer to hold the entire entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the devices were not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the two devices that have been distributed without a release from FDA (copy enclosed).

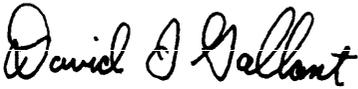
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Fernando Guevara  
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Your written reply should be addressed to the Food and Drug Administration,  
Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami,  
Florida 33159-2256.

Sincerely,

  
*for* Emma R. Singleton  
Director, Florida District

cc: Pronto Cargo Brokers, Inc.  
7330 N.W. 66<sup>th</sup> Street  
Miami, Florida 33166-3009

Thomas Winkowski  
Port Director  
U. S. Customs Service  
P. O. Box 02-580  
Miami, Florida 33102-5280