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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Ref: Customs Entry No.: AV3-0009539-3
Product: Laser Surgical Instrument

WARNING LETTER

FLA-01-19

November 29, 2000

Paul Underwood
Perspective International
9562 Doral Boulevard
Miami, Florida 33178

Dear Mr. Underwood:

The Food and Drug Administration (FDA) attempted to examine a shipment of a laser surgical instrument offered for entry into the United States by your firm on August 10, 2000, under the above referenced entry number, and found that the shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the device was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the laser surgical instrument that was distributed without a release from FDA (copy enclosed).

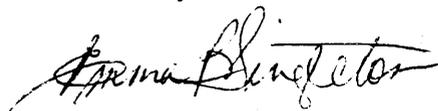
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements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

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Your written reply should be addressed to the Food and Drug Administration,
Attention: Carlos W. Hernandez, Compliance Officer, P. O. Box 59-2256, Miami,
Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Emma R. Singleton
Director, Florida District

Enclosure

cc: Sean Brophy (CHB)
7986 N.W. 14th Street
Miami, Florida 33126

U. S. Customs Service
P. O. Box 02-5280
Miami, Florida 33102-5280