



September 11, 1997

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863WARNING LETTER
CHI-45-97CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald F. Albrect, M.D.
University of Illinois
College of Medicine
Department of Anesthesiology (MC 513)
1740 West Taylor Street
Chicago, Illinois 60612

Dear Sir:

On February 26, 1997, your department offered for import into the United States a shipment of sensors invoiced as fluorescent pattern monitors under U.S. Custom entry number AJ9-0017335-9. This entry was detained under sample number 879006 on March 3, 1997. The entry was refused June 6, 1997. On August 5, 1997, we received a letter from your broker, [REDACTED] (Chicago), indicating that the item is admissible and an unconfirmed device listing number was supplied. Since the product is a class III device, you were informed an IND (Investigational New Device exemption) is required. The listing number provided could not be confirmed as valid. We received a letter dated August 27, 1997, signed by William Hoffman, Ph.D., of your department, stating the sensors had been used and destroyed.

This is a violation of Title 21, Code of Federal Regulations, Section 1.90 (a copy is enclosed), which requires the importer to hold an entry intact pending receipt of a "May Proceed or Release" notice from FDA.

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

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

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Your written reply should be addressed to the attention of Robert A. Sittig, Compliance Officer.

Sincerely,

RSI

Raymond V. Mlecko
District Director

cc: William E. Hoffman, Ph.D.
University of Illinois
College of Medicine
Department of Anesthesiology (MC 513)
1740 West Taylor Street
Chicago, Illinois 60612