



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA FEDEX**

**WARNING LETTER**

March 17, 2000

Our Reference: 1832216

K.C. Chen, Ph.D, President  
Teco Diagnostics  
4925 East Hunter Avenue  
Anaheim, CA 92807

Dear Dr. Chen:

On February 25, 2000, our examination of a shipment of unfinished pregnancy test kits offered into import into the United States by your firm under entry number 110-5872017-7 revealed the entry also included "One Step Morphine Urine Dipstick Test" kits, a finished medical device. These "One Step Morphine Urine Dipstick Test" were not declared under entry 110-5872017-7. Such misrepresentation at the time of entry appears to be an attempt to circumvent FDA's statutory requirements for medical devices.

The "One Step Morphine Urine Dipstick Test" is a medical device as defined under 201(h) of the Federal Food, Drug and Cosmetic Act (Act). At the time of entry into the United States, evidence must be provided that: a notice or other information for this device was provided to the FDA as required by Section 510(k) of the Act; the device is included in a list as required by Section 510(j) of the Act; and the initial distributor has registered as required by Title 21 Code of Federal Regulations 807.20 (a)(4).

Failure to prevent future violations may result in regulatory action, without further notice, such as seizure, injunction or detention without physical examination of future shipments.

It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Act and the regulations promulgated thereunder.

Please notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to prevent recurrence of the noted violations. Your written reply

should be addressed to the Food and Drug Administration, Attention: Mr. Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,

A handwritten signature in black ink that reads "Charles D. Moss". The signature is written in a cursive style with a large initial "C".

Charles D. Moss  
Acting Director  
San Francisco District