



FEB 28 2001

WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

Alexander Moskalenko  
Director/CEO  
Science-Production Centre  
Erevanska Street 31/1  
03087, Kiev, Ukraine

Dear Mr. Moskalenko:

We are writing you because the Food and Drug Administration (FDA) obtained information regarding the importation of the Arbor Test Microscope. This device, according to your package insert, is designed for microscopic analysis of woman's saliva for prevention of pregnancy and/or determination of favorable periods for pregnancy.

This product is considered to be a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act). Under this Act, manufacturers of medical devices are required to obtain marketing clearance for their products from the FDA before they can offer them for sale in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale in this country. You can obtain FDA's requirements on the type of information to be included in a premarket notification for this device by contacting Dr. Jean Cooper, Chief of the Clinical Chemistry Branch, at 301-594-1243. Please note that a guidance document and labeling requirements for this device can be found at <http://www.fda.gov/cdrh/ode/odec1272.html>.

Because you do not have marketing clearance from the FDA, marketing your product in this country is a violation of the Act. In legal terms, the product is adulterated under the section 501(f)(1)(B) and misbranded under the section 502(o) of the Act. Your product is adulterated under the Act because you did not submit information that shows your device is safe and effective. Also, your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed in this country.

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Also, you may be subject to Section 5 of the Federal Trade Commission Act (15 U.S.C. §45), which prohibits deceptive acts or practices in or affecting commerce. Also, Section 12 of the Federal Trade Commission Act (15 U.S.C. §52) prohibits the dissemination of any false advertisement to induce purchase of any food, drug, or device.

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 issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for medical device manufacturers by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or the Internet at <http://www.fda.gov/cdrh/devadvice/11.html>.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 days (15) working days from the date that you receive this letter what steps you are taking to correct the problem involving the sale and exportation to this country of an unapproved/uncleared product by your company. We also ask that you explain how you plan to prevent this from happening again and what you will do about unapproved/uncleared products currently in retail outlets. If you need more time, please let us know why and when you expect to complete your correction. Please direct your response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, Center for Devices and Radiological Health, 2094 Gaither Road, HFZ-321, Rockville, MD 20850.

Your device may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected. In order to remove this device from detention, it will be necessary for you to provide the information requested above. Once an adequate response has been received, FDA will conduct an inspection of your facility to determine compliance with all regulations. As soon as the inspection has taken place, and the implementation of all required actions has been verified, your device may resume entry into this country.

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If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, In Vitro Diagnostic Devices Branch, HFZ, 2098 Gaither Road, Rockville, MD 20850 to attention of Dr. Augustin Gonzalez-Licea.

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. D. Spears" with a stylized flourish at the end.

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health