



WARNING LETTER

FEB 13 2004

Certified Mail
Return Receipt Requested

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

Terrence J. Fortino
President, CEO
Mid-Atlantic Diagnostics, Inc.
438 N. Elmwood Road
Marlton, New Jersey 08053

Dear Mr. Fortino:

We are writing to you because on June [REDACTED] an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the Stripper-PGD micropipette which is made and marketed by your firm.

Under a United States law, the Federal Food, Drug and Cosmetic Act, this product is considered to be a medical device because it is used to diagnose or treat a medical condition. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of our databases disclosed that your firm obtained premarket notification (510(k)) clearance [REDACTED] for another device called the Stripper Assisted Reproduction Microtool (the Stripper). We reviewed [REDACTED] and confirmed that a 510(k) would be required for the Stripper-PGD because it differs significantly in intended use from the Stripper.

Information collected during our inspection of your firm, as well as information on your firm's Internet web site, <http://www.midatlanticdiagnostics.com> indicate that the Stripper is intended for use to manipulate and transfer zygotes and embryos during IVF, ICSI and assisted hatching procedures prior to re-implantation. The Stripper-PGD is intended for use to transfer of a blastomere from a six or eight cell pre-embryo to a reaction vessel or slide for the

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purpose of pre-implantation genetic diagnosis (PGD) or analysis. A blastomere is distinctly different from an oocyte, zygote, or embryo, and PGD is distinctly different from IVF, ICSI, and assisted hatching procedures.

The investigator advised you during the inspection close-out meeting that the Stripper-PGD would require a separate 510(k). You stated you would contact FDA's CDRH for a final decision. To date, we have not received any correspondence from you concerning the Stripper-PGD.

The kind of information you need to submit in order to obtain marketing clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. Your 510(k) should also address the following intended uses: (1) to strip cumulus and corona cells surrounding the pre-embryo in preparation for PGD, and (2) to safely transfer blastomeres through various media and solutions so that they may undergo genetic analysis as part of PGD. FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or

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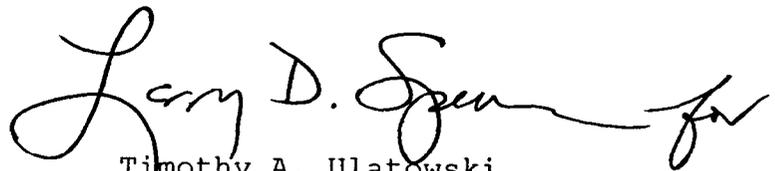
assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Sharon Murrain-Ellerbe, HFZ-332, 2098 Gaither Road, Rockville, MD 20850.

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 manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Ms. Murrain-Ellerbe at 1-301-594-4616.

Sincerely yours,

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

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices
and Radiological Health