



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN 12 2004

WARNING LETTER

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

FEDERAL EXPRESS

Mr. Jan Marek, CSc.
Director of MediCom a.s.
Zeniskova 1647
14900 Praha 4, Czech Republic

Dear Mr. Marek:

We are writing to you because on October 3, 2003, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the Maestro Low Level laser Therapy Device (Maestro) 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.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. 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

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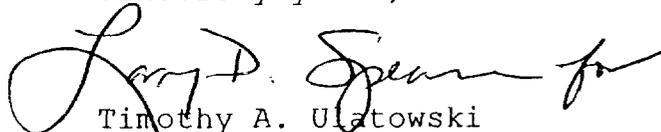
limited to, detaining without physical examination upon entry into the United States all Maestro devices manufactured by your firm. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary 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 Carol Shirk, Consumer Safety Officer, General Surgery Devices Branch, Division of Enforcement A, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 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 Carol Shirk at 1-301-594-4618.

Sincerely yours,



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

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