



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M32511

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 1999

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Thomas M. Patton
President & CEO
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Dear Mr. Patton:

During an inspection conducted on September 8, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as Conserve PLUS (metal-on-metal, hip resurfacing prosthesis), which is made and marketed by your firm.

The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either, 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. Because you do not have marketing clearance from FDA, marketing your product is in 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 Federal Food, Drug, and Cosmetic Act (the Act). Your product is adulterated under the Act because you did not obtain premarket approval (PMA) based on information developed by you that shows your device is safe and effective. 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.

The Conserve PLUS does not meet the criteria of a custom device and is not exempt from premarket notification under 21 CFR 807.85 (title 21 Code of Federal Regulations part 807, section 85), compliance with the investigational device exemption regulation under 21 CFR 812.3, or premarket approval under section 520(b) of the Act. The inspection revealed that Wright Medical Technology, Inc., had shipped [redacted] Hemi Resurfacing Shell components and [redacted] Femoral Resurfacing Head components to a single physician. The inspection also revealed that these components were ordered in [redacted] determined sizes. The Hemi Resurfacing Shell components were sold in [redacted].
The Femoral Resurfacing Head components were sold in [redacted]. Many of the shipments consisted of multiple devices of the same size and many shipments contained large numbers of devices [redacted]. femoral resurfacing head components were shipped to the physician on or about December 4, 1998, [redacted] of which were of a single size [redacted]. Hemi resurfacing shell components were shipped to the physician on or about June 21, 1999 [redacted] of which were of a single size.

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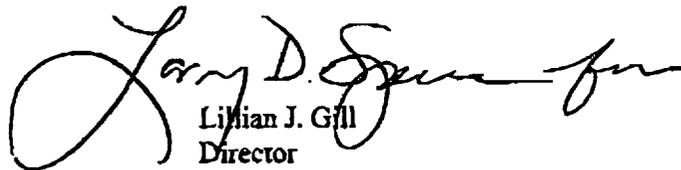
A custom device, among other things, must be intended for use by an individual patient named in a prescription or be intended to meet the special needs of a physician in the course of their professional practice. The Conserve PLUS is neither intended for use by an individual patient named in a physician's order and made in a specific form for that patient, nor is it intended to meet the special needs of an individual physician in the course of his professional practice. A special need is a need that is unique to the physician as an individual. A device that meets a need that is shared by others in the field, and is not unique to them as individuals, is not a special need. A device that meets a need that is shared by others in the field can be tested through clinical investigations and can be subject to the PMA requirements in order to ensure that it is safe and effective, and is not a custom device.

The custom device provision was not meant for the circumvention of otherwise applicable provisions of the Act, including section 520(g). This is to inform you that, in accordance with 21 CFR 812.20(a), an investigational device exemption application must be submitted to FDA for the Conserve PLUS device, and the device may only legally be distributed after FDA has approved the application.

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 assessing civil money penalties. Also, other Federal agencies are informed about 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 in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again with this or any other product. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Edgardo Santiago, Chief, Orthopedic, Physical Medicine, and Anesthesiology Devices Branch, Office of Compliance, 2094 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health