



APR 11 2001

WARNING LETTER

VIA FEDERAL EXPRESS

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

Dear Mr. Patton:

We reviewed the information provided by Mr. Robert W. Churinetz to Mr. Edgardo Santiago, of my office, in an August 31, 2000, letter involving the product known as AlloMatrix™ Human Demineralized Bone Matrix Putty (AlloMatrix™) which is made and marketed by your firm. Your letter was in response to our August 3, 2000, letter in which we requested clarification of the regulatory status of AlloMatrix™. In your letter, you said that prior to the initial distribution of AlloMatrix™ in the United States, you concluded, and continue to conclude, that you are not required to submit a premarket notification to the Food and Drug Administration (FDA). You further said that the reason for your conclusion was that AlloMatrix™ is not a device but a Human Tissue, as described in 21 CFR 1270.3(j), and, therefore, exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act).

We disagree with your conclusion that AlloMatrix™ is not a device. As you say in your letter, AlloMatrix™ contains [REDACTED] and [REDACTED]. These two components provide a [REDACTED] that [REDACTED] is by itself a medical device. [REDACTED] is a [REDACTED] of two [REDACTED] used as a [REDACTED] for these [REDACTED]. Although [REDACTED] is a tissue product, when combined with a medical device, as in AlloMatrix™, the finished product is regulated as a device.

Under the Act, this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure of function of the body. 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 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. You confirmed this fact in your letter.

Because you do not have marketing clearance from 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 adulterated under the Act because you did not obtain premarket approval based on information developed by you that

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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.

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 the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

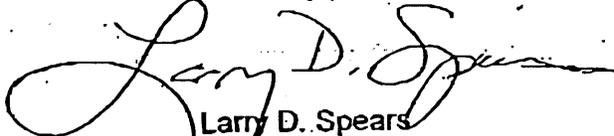
It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If 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, HFZ-343
Division of Enforcement III, Office of Compliance, CDRH,
2098 Gaither Road
Rockville, MD 20857

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 Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

If you have specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact Mr. Santiago at (301) 594-4659, extension 109.

Sincerely yours,



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

cc: Robert W. Churinetz
Vice President of Operations