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

WARNING LETTER**MAR 1 2001**

Ms. Paula Joyce, Manager
Quality Assurance and Regulatory Affairs
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Dear Ms. Joyce:

This is in follow up to our letter of November 3, 2000, addressed to Mr. Richard F. Marshall, regarding information we received that indicates that your firm is marketing an esophageal anti-reflux z-stent without the necessary clearance from the U.S. Food and Drug Administration. To date, we have not had a response to our letter.

We acknowledge that Wilson-Cook currently has clearance to market an esophageal z-stent under premarket notification K920218. However, the stent granted clearance does not have an anti-reflux valve. Therefore, your anti-reflux z-stent does not have the necessary clearance and is considered misbranded within the meaning of 502(o) of the Federal Food, Drug, and Cosmetic Act (the Act).

Furthermore, because this device has not yet been found substantially equivalent to a predicate device through the review of a 510(k) submission, this device is also adulterated within the meaning of section 501(f)(1)(B) of the Act. This is based on the fact that it has been offered for sale in interstate commerce for the first time after May 28, 1976, thereby statutorily classifying it as a Class III device. It does not have, as required under section 515(a), an approved application for premarket approval (PMA), and it is not exempt from such requirement under an Investigational Device Exemption (IDE) (section 520(g)).

You should take prompt action to correct these violations. Continued marketing of this device without the required FDA clearance could result in regulatory action by the agency without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

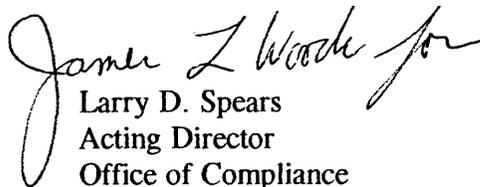
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please reply to this office, in writing, within 15 working days of receipt of this letter, describing the specific steps you have taken to correct the noted violations including steps to prevent the recurrence of similar violations. By copy of this letter the appropriate FDA local office is being advised of these violations.

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Your response should be sent to the attention of Mr. Ronald Swann, Dental, ENT and Ophthalmic Devices Branch, HFZ-331, at the letterhead address.

Sincerely yours,

A handwritten signature in cursive script that reads "James Z Woods for". The signature is written in black ink and is positioned above the typed name of the signatory.

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