



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 02 2005

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Billy G. Pierson #907177
Pack 1
2400 Wallace Park Rd
Navasota, TX 77869

Re: 2005A-0014

Dear Mr. Pierson:

This letter is in reply to your letters to the Food and Drug Administration (FDA) dated January 03 and 10, 2005, concerning complaints about your treatment with the device "AMBI" compression hip screw.

Thank you for contacting us. We hope our response helps to clarify some issues for you regarding the "AMBI" compression hip screw. In both of your letters you state that the product is either investigational or is in an experimental protocol.

It appears that this product may have been cleared for marketing and thus may have been implanted in you under an existing marketing clearance obtained in 1989 or thereafter. You appear to have received the device in 2001, considerably after the clearance date. If the device you received was a product cleared by FDA for marketing, it is unlikely to have been implanted under an investigational study.

You appear to believe, however, that this is an investigational or experimental device. If a manufacturer or sponsor is considering doing an investigational study, they are expected to submit an investigational device study protocol and plan to the FDA and to an institutional review board (IRB) for approval prior to initiating a study. Our review of FDA's database fails to identify that this product is in any study.

If you know that you received this device as part of an FDA approved investigational study, you should provide all information identifying the investigation to FDA. This would include any copies of the investigational protocol, the exact name of the investigation, a copy of the informed consent document, any other information identifying the actual study, and the investigational device exemption (IDE) number. Regarding the IDE number, it will be identified in a form similar to the following identification "G050000" (where the number is preceded by a "G" and followed by a number identifying the year of the IDE submission, e.g. "05," and four additional numbers). This information would help us determine if additional action is necessary because the product was not cleared for marketing when you were implanted.

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You have also submitted a MedWatch form (MW4003197). Since, as noted above, it appears from your communications that this is not an investigational device, MedWatch is the appropriate method to report problems with this device. The agency will review your MedWatch report and take any appropriate follow up action that may be indicated.

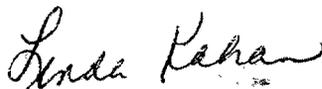
We have contacted Mr. Les Weinstein, the Ombudsman in the Center for Device and Radiological Health (CDRH) and discussed your complaints with him. He has agreed to be the contact point for further interaction if additional communication is necessary. This would provide one central point of contact so that your issues can be centrally handled. His contact information is below:

Mr. Les S. Weinstein
Ombudsman, HFZ-005
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd
Rockville, MD 20850
Telephone: 301-827-7991

Your complaint appears to focus on the physician involved and the actual surgery, rather than the performance of the device. FDA is a regulatory body commissioned to ensure that products used by the American public are safe and effective for the purposes for which they are intended. FDA does not regulate the practice of medicine. There are other mechanisms available for resolution of these issues, including state medical boards. This may be the most appropriate means by which you can resolve the issues you have identified.

If you have any further questions, please contact Mr. Weinstein.

Sincerely yours,



Linda Kahan
Deputy Director
Center for Devices and
Radiological Health