

Memo of Telephone Conversation

Bob Gatling

Between: Bob Gatling, Director, Program Operations Staff, ODE, HFZ-404

And: Mary Masters
PO Box 82043
San Diego, CA 92138
619-462-1464

Date: June 29, 2001

Subject: Petition for Declaration Regarding and Endosseous Implant

I called Ms. Masters and told her that her petition was had been transferred to our office. I told her I was not familiar with a Petition for Declaration under the citation in her petition. In addition, it was not clear from her letter exactly what she wanted from FDA. She said she had an endosseous implant installed in 1990, which was before FDA cleared the device for market. She said the device was cleared in 1994. She has had problems with the device. She is in a lawsuit with the manufacturer over the device. I told her I would have to check with some others in FDA to find out how to process the petition.

July 6, 2001

I called Ms. Masters to further clarify her need. What she needs is a declaration from FDA indicating when the device was cleared for market. The declaration is needed for her lawsuit. She said she had all the details regarding the marketing submissions and she will fax them to me. She also said she needed the Petition to be docketed for the court case. I told her that the citation in her petition would not get her the information she needed. I also told her that we could probably get her the information without the petition. I told her that the petition would be forwarded to Dockets and I would wait for her fax.

01P-0303

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