DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 1, 2013

Jeffrey G. Thomas DBA
Thomas Law Company
201 Wilshire Blvd., Suite A22
Santa Monica, CA 90401

Dear Mr. Thomas:

Your petition to the Food and Drug Administration on behalf of Ms. Marteen Moore, requesting the following actions be taken as it pertains the sponsor of Duraseal® Spinal Sealant to complete enrollment in its post-approval study of infection rates associated with use of the Spinal Sealant ("product"), to investigate risks disclosed in serious adverse effects that were not discussed in the PMA, to investigate the sponsor's compliance with its duties to report serious adverse effects to the Food and Drug Administration, to order such revisions in the Spinal Sealant's labeling and/or package inserts as are appropriate to the findings of the Agency, and to disclose reporter's identities and contact information, was received by this office on 8/01/2013. It was assigned docket number FDA-2013-P-0944/CP1, and it was filed on 8/01/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an Agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)