



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

November 19, 2002

Dear Panel Member:

Enclosed is the latest amendment (Amendment 7) submitted by CTI for their PMA. This amendment contains CTI's responses to 15 issues that we raised with the company.

You should now have received the following documents:

First mailing-- A copy of CTI's PMA summary dated September 6, 2002.

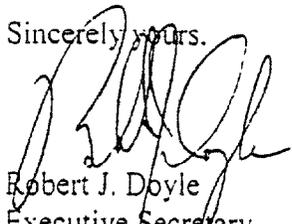
Second mailing-- A portion of the PMA (containing the clinical section of the PMA, several appendices, Amendments 4 and 5), our deficiency letters and a PMA memorandum by Dr. William Sacks, dated October 3. In this mailing, we indicated that this material replaced the September 6 material. Later, we sent you an e-mail asking that you disregard the October 3 Sacks memorandum. It was preliminary and contained some inaccuracies and it is now superseded by Amendment 7.

Current mailing-- Amendment 7 responding to our issues.

Please return two items to us at your earliest convenience: a) the first mailing and b) the October 3 Sacks memorandum that was included in the second mailing. We expect to send you one more mailing prior to the Panel meeting.

We ask that you review, in advance of the meeting, the items underlined above. If you have any questions, please contact me.

Sincerely yours,



Robert J. Doyle
Executive Secretary
Radiological Devices Panel

Enclosure