

Parts of the PMA 890057 Supplement 14, Amendment 1 that the FDA thinks should be sent to the panel

1) summary - pages 8 through 33.

2) pages 105 through 160; this includes the clinical trial design, a list of study sites, a listing of outcomes and a list of reported adverse events. (the summary pages 8-33 includes all the statistical information that is duplicated in pages 161-169, so pages 161-169 should not be included).

3) Pages 170-171 (list of patients who died on study).

4) Pages 485 through 601. Operators manual.

5) The additional material we requested as a result of the review and identified in a separate file accompanying this file should also be sent to the panel.

We did not include any published material references from the PMA; Krishnan and Brower, Chest 2000, which we cite, seems to summarize the prior work fairly. If there are specific additional published references from the PMA you would like sent to the panel, please let us know.

Similarly if there is other material from the PMA you think should be sent to the panel, please let us know.