

Dear Mr. Alan Schwartz,

We at Panasonic wanted to take this opportunity to thank you for the great work that you and Jigar have done. Thanks to your diligent efforts, we were able to attain the goals that we had set forth. We were almost positive that we would end up going to Class II with the requirement of needing a 510K, based on other consultant's comments. Instead, we were elated to find out via 513G submission (which MDI had suggested), that the product was actually Class I and did NOT require 510K. I can also say that the cost would have been several times higher if we had gone through the other consultant instead of going through MDI. (Shame on the other consultant; I will not name names.)

Again, we thank Alan Schwartz and his team of experts for making the process so much easier than we had thought. Too bad FDA does not operate as professionally as MDI does. (Our 513G review by FDA should have taken 60 days but they ended up taking 150 days!)
Take care!

Best regards,



Yasuhiro Fujii



Takaaki Yoshikawa

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