

ATTACHMENT "B"

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David W. Feigal, Jr., M.D., M.P.H.
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Dear Dr. Feigal:

I am writing this letter on behalf of the Johns Hopkins Hospital to request your consideration for SterilMed, Inc. to be given a time extension for completion of their PMA.

We have been working with SterilMed to develop a process for resterilizing solid ablative catheters for use in Cardiac Electrophysiology. Historically, Johns Hopkins has done resterilization within the institution, and our review of this practice demonstrated no incidence of untoward effects to the patients or the staff. However, with the new FDA guidelines, it was beyond the financial capabilities of Johns Hopkins to submit a PMA for the reprocessing of electrophysiology catheters. We have been working with SterilMed in order to have them submit a PMA that would allow us to work with them to provide safe, well-documented, and tracked catheters for reuse. The main beneficiaries of this practice will be patients and their insurers, who will be provided safe equipment at reduced cost. We are very willing to utilize the FDA's request of more controlled means of reprocessing catheters, however we need more time to meet the documentation needed for the PMA.

Due to the very short time given from the initial announcement of the submission dates and the initially unclear process needed to make this application acceptable, we have not been able to provide SterilMed with adequate numbers of catheters for resterilization study. As one of their PMA beta-sites, we have not been able to

provide clinical feedback in a timely manner. It is our hope that pressures from original manufacturers would not eliminate this small company's opportunities to provide a service that would greatly benefit our patients. Additional time would be essential to allow SterilMed to fully study their process with a variety of catheter brands and to assure the industry of their superb quality.

All of our experiences with SterilMed have been of the highest professional quality. We have been using them for reprocessing of diagnostic catheters, and they have contributed to our ability to hold patient costs to a minimum. **An additional benefit of this interaction is the improved patient care from a level of comfort provided the physician who can use a variety of catheter designs and shapes without incurring the guilty feeling that he/she has dramatically increased the cost to the patient. We feel that this is an underappreciated, but real, issue.**

Please allow SterilMed the additional time needed to collect the additional clinical data. Forcing us to stop reprocessing ablative E.P. catheters will greatly increase costs for our patients and will limit physician tools to complete an already difficult job.

Respectfully submitted,

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