DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Patrick Fleischhacker
V.P. Regulatory Affairs and Quality Control
SterilMed, Inc.
c/o Ms. JeanAnn Hurm
Alquest
11660 Wayzata Boulevard
Minnetonka, MN 55305-2010

Docket No. 01P-0346

Re: P010006
Reprocessed Cardiac Diagnostic/Ablation Catheters

Dear Mr. Fleischhacker:

This is in response to your August 8, 2001 citizen petition requesting an extension of enforcement discretion relating to the premarket approval (PMA) requirements under sections 513 and 515 of the Federal Food, Drug, and Cosmetic Act applicable to reprocessed single use devices. Previously, FDA issued a guidance on August 14, 2000 entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." This guidance stated that FDA intended to exercise enforcement discretion with respect to premarket submission requirements for reprocessors of class III devices until August 14, 2001, provided that FDA received a PMA application no later than February 14, 2001, and FDA approval by August 14, 2001.

You requested that FDA extend the enforcement discretion period beyond the August 14, 2001 approval date to "allow submission of a completed PMA until August 14, 2002" and "that FDA allow continued marketing during FDA review of the completed PMA."

After considering the reasons stated in your petition, we are granting your request for an extension in part. We understand that given the extensive information required in a PMA, additional time is reasonable to gather the information necessary for FDA review and to gain its approval. However, we do not believe that the time period of your requested extension is reasonable.

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Accordingly, FDA is extending the timeframe for a period of 6 months to obtain FDA approval, and does not intend to enforce its premarket requirements with respect to Sterilmed, or any other reprocessor of a single use class III device who has already filed a PMA, until February 14, 2002. This extension, however, does not preclude the agency from taking immediate action if the agency becomes aware of additional risks posed by the product.

Sincerely Yours,

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health