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12/2/99

Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Rd.
Rockville MD 20850
FAX # (301) 594 - 4672

RE: Sterility of Reprocessed Single Use Medical Devices

Dear Mr. Spears:

Recently, I learned that the FDA has proposed a new policy to regulate reprocessors of single use medical devices and will hold a "town meeting" on December 14th in Maryland to receive input on this new policy. Unfortunately, I am unable to attend the town meeting but I would like to submit my comments. Please accept this letter as my formal comment in opposition of the proposed new policy.

I am a Gastroenterologist from San Diego County in California. Pursuant to the above, I am very concerned about the health and welfare of my patients. Specifically, I am concerned about the potential for patient injury due to the spread of infectious diseases and device failures caused by the inappropriate reprocessing of single use labeled devices. In today's cost cutting environment, it is proper to look at all possible areas to save money, but reprocessing plastic single use devices such as biopsy forceps, sphincterotomes, electrophysiology catheters and angioplasty catheters is simply not a safe avenue to pursue until these reprocessed devices receive FDA approval for reuse.

There is no medical benefit to the patient when a reused single use device is used. It is my understanding that patients do not receive lower healthcare costs nor are they informed when a reused device is used. Without such knowledge, patients cannot protect themselves. Reprocessing a single use device for reuse changes the device into a reusable device. Reprocessors of single use devices should be regulated in the same manner as original equipment manufacturers using the existing FDA regulations for reusable devices to ensure patient safety.

Sincerely,

Robert A. Brenner MD
Robert A. Brenner, MD

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