DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2001

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Mr. Don Selvey
Vice President, Regulatory Affairs & Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: P010011
Reprocessed Electrophysiology Ablation Catheters

Dear Mr. Selvey:

FDA received a 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.

After considering the information in this petition, FDA believes that additional time is warranted, and is extending the timeframe for reprocessors who have already filed PMAs for a period of 6 months to obtain FDA approval, and does not intend to enforce its premarket requirements with respect to those reprocessors of single use class III devices 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

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