



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 19, 2000

Jeffrey R. Dahlen, Ph.D.
Principal Scientist, Clinical Regulatory Affairs
Biosite Diagnostics, Incorporated
11030 Roselle Street
San Diego, CA 92121

Dear Dr. Dahlen:

Your petition requesting the Food and Drug Administration to reclassify Triage B-Type Natriuretic Peptide (BNP) Test (K003475) as a Class II device was received by this office on 12/19/00. It was assigned docket number 00P-1675/CCP 1 and it was filed on 12/19/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

00P-1675

ACK1