



FILE COPY

March 6, 2002

Eric S. Fain, M.D., Senior Vice President
Clinical Engineering and Regulatory Affairs
St. Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91342

Dear Dr. Fain:

Your petition requesting the Food and Drug Administration to allow for electronic labeling to Meet 201(m) of FD&C Act in regard to a programmer/computer that is required to be used to interact with an implanted pulse generator was received by this office on 03/05/02. It was assigned docket number 02P-0089/CP 1 and it was filed on 03/05/02. 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
Docket's Management Branch

02P-0089

ACK1