



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

September 22, 2000

Neal E. Fearnot, Ph.D.  
President  
Cook MED Institute, Incorporated  
1400 Cumberland Avenue  
West Lafayette, IN 47906

Dear Dr. Fearnot:

Your petition requesting the Food and Drug Administration to reclassify PTCA balloon catheters from Class III to Class II was received by this office on 09/21/00. It was assigned docket number 00P-1533/CCP 1 and it was filed on 09/21/00. 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,

A handwritten signature in black ink that reads "Lyle D. Jaffe".

Lyle D. Jaffe  
Dockets Management Branch

00P-1533

ACK 1