



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 27, 2007

**FILE COPY**

Thomas J. Quinn  
411 Tyburn Drive  
Wexford, PA 15090

Dear Mr. Quinn:

Your petition requesting the Food and Drug Administration to enforce performance standards contained in 21 CFR 10.20(g)(h), 1020.33(c) and 21 CFR 1040.10(h); enforce 21 CFR 820.170 requiring manufacturers to supply all information for installations of all installable medical devices regardless of whether the installation is the first installation or not of the device; a means to calculate Computed Tomography dosage Index, dose profile and dosage measurement for dual tube CT system as prescribed in 21 CFR 1020.30(c); and a public response assuring that the FDA will strictly enforce the laws for all medical devices in the future, was received by this office on 08/27/2007. It was assigned docket number 2007P-0333/CP1 and it was filed on 08/27/2007. 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, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2007P-0333

ACK 1