



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

May 17, 2001

Thomas M. Tsakeris, President  
Devices & Diagnostics Consulting Group, Inc.  
16809 Briardale Road  
Rockville, MD 20855

Dear Mr. Tsakeris:

Your petition, on behalf of Microgenics, Inc., requesting the Food and Drug Administration to reclassify from Class III to Class II in vitro diagnostic tests for measurement of cyclosporine concentration in whole blood was received by this office on 05/16/01. It was assigned docket number 01P-0235/CCP 1 and it was filed on 04/04/01. 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

01P-0235

ACK 1