Copy 2

DEVICES & DIAGNOSTICS CONSULTING GROUP, INC.

Regulatory Affairs Consultants

Thomas M. Tsakeris
President

April 4, 2001

4362 '01 MAY 16 A9:30

Regulations Staff (HFZ-215)
Office of Health and Industry Programs
FDA Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

Re: Section 513(f) Petition for Reclassification
Cyclosporine Immunoassay

Dear Sir/Madam:

On behalf of Microgenics, Inc. we have submitted one original and two copies of a petition under section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act (Act) requesting FDA issuance of an order reclassifying from Class III to Class II *in vitro* diagnostic tests for measurement of cyclosporine concentration in whole blood. The test results are intended for use as an aid in the management of cyclosporine administration to recipients of heart, kidney and liver transplants. More specifically we request:

- All currently approved in vitro Cyclosporine tests, as well as all new proposed Cyclosporine tests, be reclassified as class II devices.
- The FDA Review Criteria for Industry regarding Cyclosporine PMAs (released 1/24/92) be re-directed to serve as a Special Control applicable to 510(k) premarket notifications cyclosporine test devices and, thus, can be the basis for FDA's review of all new proposed cyclosporine test devices.
- That FDA review, for the purpose of making a substantially equivalent determination, comparative performance characteristics data for Microgenics, Inc.'s CEDIA® Cyclosporine Plus Assay (formerly Boehringer-Mannheim Corporation CEDIA® Cyclosporine Assay), provided herein in Appendix IV (a) and (b) of this petition.

In the preparation of this reclassification petition we have followed the applicable procedural requirements under 21 CFR 860.123 and 21 CFR 860.134.

As mentioned above to enable our commercial distribution of the CEDIA® Cyclosporine Plus Assay, this petition includes information required under 21 CFR 807.87 to demonstrate the substantial equivalence of CEDIA® Cyclosporine Plus Assay to currently FDA-approved cyclosporine test devices. Appendix (a) and (b) of this petition contain exhaustive analytical and clinical data demonstrating the comparative

Devices & Diagnostics Consulting Group, Inc.
16809 Briardale Road, Rockville, MD 20855
Tel: (301) 330-2076 Fax: (301) 330-2568
E-mail: ttsak@erols.com

01P-0235

CCP 1

performance characteristics of the CEDIA® Cyclosporine Plus Assay to other commercially available ("predicate") cyclosporine assays.

As set forth in section 513(f)(2)(B) of the Act, FDA may for good cause shown refer a section 513(f) reclassification petition to an appropriate FDA advisory panel for review and recommendation before making a decision on the petition. We believe that panel review is unnecessary in this case because FDA advisory panels have previously reviewed and made recommendations on PMAs and applicable testing guidance for cyclosporine immunoassays.

Microgenics, Inc. is requesting this action based on the merits of this petition as well as on discussions with CDRH staff. Microgenics, Inc. is also aware that FDA has filed on 02/22/01 a similar reclassification petition submitted earlier this year by Dade Behring, Inc. We have reviewed this petition available for public display at FDA Dockets Management Branch (docket number 01P-0119/CCP). As many of the points raised in the Dade Behring petition are congruent with the points raised in this petition we support the Dade Behring petition and request that both petitions be considered and processed concurrently.

If clarification or additional information is needed, you may contact me by phone at 301-330-2076 or by fax at 301-330-2568 or e-mail (ttsak@erols.com)

Sincerely,

/ Thomas M. Tsakeris

Thomas M. Tsakeris
Devices & Diagnostics
Consulting Group, Inc. and
Regulatory Consultant for
Microgenics, Inc.