

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

K032842

**B. Analyte:**

Cyclosporine Control Material

**C. Type of Test:**

Control Material

**D. Applicant:**

Microgenics Corporation

**E. Proprietary and Established Names:**

Microgenics Cyclosporine Controls

**F. Regulatory Information:**

1. Regulation section:  
21CFR862.3280
2. Classification:  
Class I
3. Product Code:  
LAS
4. Panel:  
91

**G. Intended Use:**

1. Intended use(s):
2. Indication(s) for use:  
The Microgenics Cyclosporine Controls, consisting of levels 1 through 5 are in vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine.
3. Special condition for use statement(s):
4. Special instrument Requirements:

**H. Device Description:**

The Microgenics Cyclosporine whole blood controls are prepared from human whole blood, lyophilized, with stabilizers. Target concentrations for the five control levels are approximately 70, 200, 350, 700 and 1600 ng/ml of cyclosporine.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
CEDIA Cyclosporine High Range Controls  
Bio-Rad Lypocheck Whole Blood Control
2. Predicate K number(s):  
K030616, K022041
3. Comparison with predicate:  
This control material is similar to the predicate in terms of intended use, matrix, and reconstituted stability. Additional cyclosporine levels are included in these controls, compared to the predicate devices.

**J. Standard/Guidance Document Referenced (if applicable):****K. Test Principle:**

N/A. This 510(k) describes control material only.

**L. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

Intra-assay reproducibility was evaluated using the CEDIA Cyclosporine Plus Assay. Twenty one replicates were analyzed in three runs on two Hitachi 911 analyzers. Results are shown below:

	Run1	Run2	Run3
Control 1: avg	63.2	63.8	59.1
SD	6.0	5.4	5.6
Control 2: avg	175.6	183.8	170.1
SD	4.8	7.8	7.8
Control 3: avg	314.8	321.8	326.5
SD	10.5	7.1	7.9
Control 4: avg	643.7	668.4	641.9
SD	31.4	24.7	25.9
Control 5: avg	1435.2	1419.9	1480.1
SD	33.6	43.6	48.6

b. *Linearity/assay reportable range:*

N/A

c. *Traceability (controls, calibrators, or method):*

Stability of the reconstituted controls was established by reconstituting each control level with the diluent supplied to users, storing at 2-8 degrees C and testing between days 0 and 14.

Acceptance criteria for recovery are  $\pm 10\%$ .

Stability of lyophilized material is based on evaluation of the previously cleared Microgenics controls, which are identical in formulation and on ongoing real-time stability studies.

Value assignment is based on replicate analyses of control solutions using the Microgenics CEDIA Cyclosporine Plus Assay on Hitachi 900 series analyzers. The manufacturer recommends that each laboratory establish its own means and acceptable ranges and use the ones provided only as guides.

*d. Detection limit:*

N/A

*e. Analytical specificity:*

N/A

*f. Assay cut-off:*

N/A

2. Comparison studies:

*a. Method comparison with predicate device:*

N/A

*b. Matrix comparison:*

N/A

3. Clinical studies:

*a. Clinical sensitivity:*

N/A

*b. Clinical specificity:*

N/A

*c. Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:

5. Expected values/Reference range:

**M. Conclusion:**

I recommend the Microgenics Cyclosporine controls are substantially equivalent to the predicate device.