

K053061 EMIT 2000 CYCLOSPORINE SPECIFIC ASSAYFeb 6, 2006
98 days to decisionK053061 · Product code: **MKW** · Toxicology
Source: <https://www.510kdatabase.net/k053061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cyclosporine (MKW)
Date received	Oct 31, 2005
Decision date	Feb 6, 2006
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	YUK-TING LEWIS
510(k) history	343 submissions · 343 cleared · 1978-2010

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