

**K003341 EMIT 2000 TOBRAMYCIN ASSAY EMIT 2000  
TOBRAMYCIN CALIBRATORS**Jan 22, 2001  
89 days to decisionK003341 · Product code: **KLB** · Chemistry  
Source: <https://www.510kdatabase.net/k003341/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Tobramycin (KLB)
Date received	Oct 25, 2000
Decision date	Jan 22, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syva Co., Dade Behring, Inc.</b>
Location	San Jose, CA, US
Contact	PAUL L ROGER
510(k) history	19 submissions · 19 cleared · 2000-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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