

K060853 ONLINE TDM TOBRAMYCINJun 9, 2006
72 days to decisionK060853 · Product code: **KLB** · Toxicology
Source: <https://www.510kdatabase.net/k060853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Tobramycin (KLB)
Date received	Mar 29, 2006
Decision date	Jun 9, 2006
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	DIMIRIS DEMIRTZOGLU
510(k) history	264 submissions · 263 cleared · 1999-2013

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