

K060998 QMS TOBRAMYCINJul 21, 2006
101 days to decisionK060998 · Product code: **LCR** · Chemistry
Source: <https://www.510kdatabase.net/k060998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Tobramycin (LCR)
Date received	Apr 11, 2006
Decision date	Jul 21, 2006
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	EARL E KNIGHT III
510(k) history	28 submissions · 28 cleared · 1988-2007

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