

K954291 OPUS TDM CONTROLSNov 20, 1995
67 days to decisionK954291 · Product code: **DIF** · Toxicology
Source: <https://www.510kdatabase.net/k954291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Sep 14, 1995
Decision date	Nov 20, 1995
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	145 submissions · 145 cleared · 1976-1997

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