FDA 510(k) Premarket Notification

K032279 ONLINE TDM AMIKA

CLEARED

Oct 10, 2003
78 days to decision

K032279 · Product code: **KLP** · Toxicology
Source: https://www.510kdatabase.net/k032279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amikacin Serum Assay (KLP)
Date received	Jul 24, 2003
Decision date	Oct 10, 2003
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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