FDA 510(k) Premarket Notification

K033879 VALIDATE TDM CALIBRATION VERIFICATION TEST SET, MODEL 126

CLEARED

Feb 27, 2004
74 days to decision

K033879 · Product code: **DKB** · Toxicology
Source: https://www.510kdatabase.net/k033879/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Dec 15, 2003
Decision date	Feb 27, 2004
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maine Standards Co.**
Location	Windham, ME, US
Contact	CHRISTINE BEACH
510(k) history	23 submissions · 23 cleared · 2001-2013