FDA 510(k) Premarket Notification

K023780 DRI PRIMIDONE CALIBRATORS

CLEARED

Feb 10, 2003
90 days to decision

K023780 · Product code: **DLJ** · Toxicology
Source: https://www.510kdatabase.net/k023780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Nov 12, 2002
Decision date	Feb 10, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Microgenics Corp.**
Location	Concord, CA, US
Contact	LAKSHMI ANNE
510(k) history	107 submissions · 106 cleared · 1985-2013