FDA 510(k) Premarket Notification

K990820 RAPIDONE - OPIATES TEST

CLEARED

Jul 15, 1999
126 days to decision

K990820 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k990820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 11, 1999
Decision date	Jul 15, 1999
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Bio Medica Corp.**
Location	Washington, DC, US
Contact	JOHN B DUBECK
510(k) history	30 submissions · 30 cleared · 1997-2017