FDA 510(k) Premarket Notification

K020792 ACETAMINOPHEN ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEM

CLEARED

Jul 11, 2002
122 days to decision

K020792 · Product code: **LDP** · Toxicology
Source: https://www.510kdatabase.net/k020792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Mar 11, 2002
Decision date	Jul 11, 2002
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Diagnostics Corp.**
Location	Medfield, MA, US
Contact	KENNETH T EDDS
510(k) history	32 submissions · 32 cleared · 2000-2003