FDA 510(k) Premarket Notification

K022096 URIC ACID ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEM

CLEARED

Mar 18, 2003
264 days to decision

K022096 · Product code: **KNK** · Chemistry
Source: https://www.510kdatabase.net/k022096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Uric, Uricase (colorimetric) (KNK)
Date received	Jun 27, 2002
Decision date	Mar 18, 2003
Days to decision	264 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