FDA 510(k) Premarket Notification

K971534 SYNCHRON SYUSTEMS DAT DRUG FREE URINE CONTROL

CLEARED

May 21, 1997
23 days to decision

K971534 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k971534/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Apr 28, 1997
Decision date	May 21, 1997
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman**
Location	Brea, CA, US
Contact	FRANK MARTE
Website	http://www.beckmancoulter.com/
510(k) history	6 submissions · 6 cleared · 1989-1999

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k971534/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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