FDA 510(k) Premarket Notification

K921977 SYNERGY SCREEN TEST, MODIFICATION

CLEARED

Oct 12, 1993
539 days to decision

K921977 · Product code: **LRG** · Microbiology
Source: https://www.510kdatabase.net/k921977/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument For Auto Reader & Interpretation Of Overnight Suscept. Systems (LRG)
Date received	Apr 21, 1992
Decision date	Oct 12, 1993
Days to decision	539 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	KARLA TOMFOHRDE
510(k) history	505 submissions · 496 cleared · 1977-2019