FDA 510(k) Premarket Notification

K983252 SYSTEM U3 FOR GENTAMICIN

CLEARED

Nov 20, 1998
65 days to decision

K983252 · Product code: **JWY** · Microbiology
Source: https://www.510kdatabase.net/k983252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 16, 1998
Decision date	Nov 20, 1998
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ab Biodisk North America, Inc.**
Location	S-17136 Solna, Sweden, SE
Contact	ANNE BOLMSTROM
510(k) history	3 submissions · 3 cleared · 1994-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k983252/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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