FDA 510(k) Premarket Notification

K905617 VISI-STAPH

CLEARED

Mar 29, 1991
105 days to decision

K905617 · Product code: **JWX** · Microbiology
Source: https://www.510kdatabase.net/k905617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Staphylococcus Aureus (JWX)
Date received	Dec 14, 1990
Decision date	Mar 29, 1991
Days to decision	105 days
Third-party review	No

APPLICANT

Company	**Connecticut Diagnostics, Ltd.**
Location	Mchenry, IL, US
Contact	JOHN ABRAHAM
510(k) history	14 submissions · 14 cleared · 1979-1991