FDA 510(k) Premarket Notification

K945660 AUTOJECT 2

CLEARED

Aug 11, 1995
267 days to decision

K945660 · Product code: **KZH** · General Hospital
Source: https://www.510kdatabase.net/k945660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Nov 17, 1994
Decision date	Aug 11, 1995
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Owen Mumford USA, Inc.**
Location	Marietta, GA, US
Contact	ROBERT E SHAW
510(k) history	10 submissions · 10 cleared · 1995-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945660/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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