FDA 510(k) Premarket Notification

K981266 AUTO-INJECTOR, SURE-INJECT 2000

CLEARED

Jul 14, 1998
98 days to decision

K981266 · Product code: **KZH** · General Hospital
Source: https://www.510kdatabase.net/k981266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Apr 7, 1998
Decision date	Jul 14, 1998
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mighty Mo, Corp.**
Location	St. Petersburg, FL, US
Contact	JOHN D'ANGELO
510(k) history	1 submissions · 1 cleared · 1998-1998