FDA 510(k) Premarket Notification

CLEARED

K973510 DUPLOJECT (0.5/1.0 ML, 2.0 ML, 5.0 ML)

Dec 8, 1997
83 days to decision

K973510 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k973510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 16, 1997
Decision date	Dec 8, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Immuno-U.S., Inc.**
Location	Rockville, MD, US
Contact	DAVID WEST
510(k) history	1 submissions · 1 cleared · 1997-1997