FDA 510(k) Premarket Notification

K882064 LO-CORE NEEDLE

CLEARED

Jul 8, 1988
52 days to decision

K882064 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k882064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 17, 1988
Decision date	Jul 8, 1988
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Device Labs, Inc.**
Location	Medway, MA, US
Contact	ELTON M TUCKER
510(k) history	6 submissions · 5 cleared · 1988-1993