FDA 510(k) Premarket Notification

K811009 PREFILLED PULSATOR SYRINGE

CLEARED

Jun 12, 1981
58 days to decision

K811009 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k811009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 15, 1981
Decision date	Jun 12, 1981
Days to decision	58 days
Third-party review	No

APPLICANT

Company	**Concord Laboratories, Inc.**
Location	Mchenry, IL, US
Website	https://www.concordlabs.com
510(k) history	42 submissions · 38 cleared · 1976-1989