FDA 510(k) Premarket Notification

K973654 VIAL-MATE RECONSTITUTION DEVICE (2B8071)

CLEARED

Oct 24, 1997
29 days to decision

K973654 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k973654/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Sep 25, 1997
Decision date	Oct 24, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	TAMIMA ITANI
510(k) history	505 submissions · 496 cleared · 1977-2019