FDA 510(k) Premarket Notification

K010623 RECONSTITUTION KIT & VIAL CONNECTOR

CLEARED

Apr 5, 2001
34 days to decision

K010623 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k010623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Mar 2, 2001
Decision date	Apr 5, 2001
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bioject, Inc.**
Location	Portland, OR, US
Contact	NANCY GERTLAR
510(k) history	9 submissions · 9 cleared · 1987-2009