FDA 510(k) Premarket Notification

K013523 CISTEM FLUID TRANSFER DEVICE, MODEL 7S2012 AND 7S2013

CLEARED

Jan 7, 2002
76 days to decision

K013523 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k013523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Oct 23, 2001
Decision date	Jan 7, 2002
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shire Biologics, Inc.**
Location	San Diego, CA, US
Contact	ANGELA ROGERS
510(k) history	1 submissions · 1 cleared · 2002-2002