FDA 510(k) Premarket Notification

K050472 LYSUS INFUSION SYSTEM

CLEARED

Mar 11, 2005
15 days to decision

K050472 · Product code: **DRA** · Cardiovascular
Source: https://www.510kdatabase.net/k050472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Feb 24, 2005
Decision date	Mar 11, 2005
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ekos Corp.**
Location	Bothell, WA, US
Contact	JOCELYN KERSTEN
510(k) history	23 submissions · 18 cleared · 2003-2008