FDA 510(k) Premarket Notification

K052071 LYSUS INFUSION SYSTEM

CLEARED

Aug 16, 2005
15 days to decision

K052071 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k052071/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Aug 1, 2005
Decision date	Aug 16, 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