FDA 510(k) Premarket Notification

K060084 LYSUS INFUSION SYSTEM

CLEARED

Feb 7, 2006
27 days to decision

K060084 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k060084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jan 11, 2006
Decision date	Feb 7, 2006
Days to decision	27 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k060084/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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