FDA 510(k) Premarket Notification

K072507 ENDOWAVE INFUSION SYSTEM

CLEARED

Oct 4, 2007
28 days to decision

K072507 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k072507/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Sep 6, 2007
Decision date	Oct 4, 2007
Days to decision	28 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/k072507/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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