FDA 510(k) Premarket Notification

K111705 EKOSONIC ENDOVASCULAR SYSTEM

CLEARED

Aug 3, 2011
47 days to decision

K111705 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k111705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jun 17, 2011
Decision date	Aug 3, 2011
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ekos Corporation**
Location	Bothell, WA, US
Contact	JOCELYN KERSTEN
510(k) history	2 submissions · 2 cleared · 2011-2020