

**K200648 EKOS PE Endovascular Device with Control System
4.0 (CS4.0)**

Aug 17, 2020
158 days to decision

K200648 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k200648/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Mar 12, 2020
Decision date	Aug 17, 2020
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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