FDA 510(k) Premarket Notification

K182487 CerusEndo Microcatheter

CLEARED

Jul 20, 2019
312 days to decision

K182487 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k182487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 11, 2018
Decision date	Jul 20, 2019
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cerus Endovascular, Inc.**
Location	Fremont, CA, US
Contact	Theresa Brandner
510(k) history	2 submissions · 2 cleared · 2019-2022