

K213314 CerusEndo Microcatheter (027)Mar 15, 2022
162 days to decisionK213314 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k213314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Oct 4, 2021
Decision date	Mar 15, 2022
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Cerus Endovascular, Ltd.
Contact	Lori Adels

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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