

K203409 MC3 Crescent Jugular Dual Lumen CatheterMay 3, 2021
165 days to decisionK203409 · Product code: **PZS** · Cardiovascular
Source: <https://www.510kdatabase.net/k203409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dual Lumen Ecmo Cannula (PZS)
Date received	Nov 19, 2020
Decision date	May 3, 2021
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mc3, Inc.
Location	Dexter, MI, US
Contact	Martha Rumford
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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