

K192786 Gatekeeper Balloon CatheterApr 25, 2020
208 days to decisionK192786 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k192786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Sep 30, 2019
Decision date	Apr 25, 2020
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arch Catheter, LLC
Location	Ninety Six, SC, US
Contact	Michael Zhadkevich
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy
Contact	Mary Vater

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192786/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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