

K182399 Park Blade Septostomy CatheterApr 4, 2019
212 days to decisionK182399 · Product code: **DXF** · Cardiovascular
Source: <https://www.510kdatabase.net/k182399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Sep 4, 2018
Decision date	Apr 4, 2019
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Rebecca Odulio
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182399/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026