

K231626 OSPREY Closed IV Catheter System (OspreyV2)Aug 31, 2023
90 days to decisionK231626 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k231626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jun 2, 2023
Decision date	Aug 31, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skydance Vascular, Inc.
Location	Pleasant Grove, UT, US
Contact	Scott Pease
510(k) history	3 submissions · 3 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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