

K243884 TAVIPILOTJul 7, 2025
201 days to decisionK243884 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k243884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 18, 2024
Decision date	Jul 7, 2025
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Caranx Medical
Location	Paris, FR
Contact	Pierre Berthet-Rayne
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243884/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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