FDA 510(k) Premarket Notification

K223050 AZUR HydroPack 18 (45-880005

CLEARED

Dec 21, 2022
83 days to decision

K223050 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k223050/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 29, 2022
Decision date	Dec 21, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	45-880010; 45-880020; 45-880035; 45-880050; 45-880060)

APPLICANT

Company	**MicroVention, Inc.**
Location	Aliso Viejo, CA, US
Contact	Riddhi Pandya
510(k) history	85 submissions · 85 cleared · 2001-2024