FDA 510(k) Premarket Notification

K244007 ArteVu

CLEARED

Jul 30, 2025
216 days to decision

K244007 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k244007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Dec 26, 2024
Decision date	Jul 30, 2025
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cardio Ring Technologies, Inc. Taiwan Branch**
Location	New Taipei City, TW
Contact	Wen-Pin Shih
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Alexia Haralambous

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