

K173483 Pure Flow External Counter-Pulsation DeviceMay 30, 2018
198 days to decisionK173483 · Product code: **DRN** · Cardiovascular
Source: <https://www.510kdatabase.net/k173483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Nov 13, 2017
Decision date	May 30, 2018
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xtreem Pulse, LLC
Location	New York, NY, US
Contact	Andrew Barile
510(k) history	4 submissions · 4 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173483/> 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 May 26, 2026