

**K202108 External Counterpulsation System, Soulaire**Aug 28, 2020  
29 days to decisionK202108 · Product code: **DRN** · CardiovascularSource: <https://www.510kdatabase.net/k202108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Jul 30, 2020
Decision date	Aug 28, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vamed Medical Instrument Co., Ltd.</b>
Location	Foshan, CN
Contact	Ji Ma
510(k) history	2 submissions · 2 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Keda Biological Tech Co., Ltd.</b>
Contact	Jet Li

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

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