FDA 510(k) Premarket Notification

K190683 External Counterpulsation System

CLEARED

Sep 10, 2019
176 days to decision

K190683 · Product code: **DRN** · Cardiovascular
Source: https://www.510kdatabase.net/k190683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Mar 18, 2019
Decision date	Sep 10, 2019
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vamed Medical Instrument Co., Ltd.**
Location	Foshan, CN
Contact	Ji Mia
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Keda Testing Tech Co., Ltd.**
Contact	Jet Li

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