

**K191955 Enhanced External Counter Pulsation Device Plus  
Omay-A**Aug 5, 2020  
380 days to decisionK191955 · Product code: **DRN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Jul 22, 2019
Decision date	Aug 5, 2020
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omay(Guangzhou)Med Technologies Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Peixian Su
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Chonconn Medical Device Consulting Co., Ltd.</b>
Contact	Kevin Wang

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191955/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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