FDA 510(k) Premarket Notification

K190101 UltraFlex IAB

CLEARED

Jun 28, 2019
157 days to decision

K190101 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k190101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Jan 22, 2019
Decision date	Jun 28, 2019
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International, Inc.**
Location	Reading, PA, US
Contact	Niyati Boghani
510(k) history	19 submissions · 17 cleared · 2003-2020

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190101/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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