

K232638 FilteredFlo Warming BlanketsOct 24, 2023
55 days to decisionK232638 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Aug 30, 2023
Decision date	Oct 24, 2023
Days to decision	55 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iob Medical, Inc.
Location	Gaithersburg, MD, US
Contact	Jonathan Kovach
510(k) history	7 submissions · 7 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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