

K202197 Astopad Patient Warming SystemSep 4, 2020
30 days to decisionK202197 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k202197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Aug 5, 2020
Decision date	Sep 4, 2020
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stihler Electronic GmbH
Location	Sound Beach, NY, US
Contact	Jens- Peter Weege
510(k) history	6 submissions · 6 cleared · 1999-2020

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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