

K233249 APPRAISE-HRIApr 5, 2024
190 days to decisionK233249 · Product code: **SAR** · Cardiovascular
Source: <https://www.510kdatabase.net/k233249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Hemodynamic Indicator With Decision Point For Military Use (SAR)
Date received	Sep 28, 2023
Decision date	Apr 5, 2024
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Surgeon General, Department of the Army (TSG-DA)
Location	Fort Detrick, MD, US
Contact	Emily Badraslionglu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	U.S. Army Medical Materiel Research & Development Command;
Contact	Chandar Thakur

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

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