

**K210862 Hemafuse System**Jul 29, 2021  
128 days to decisionK210862 · Product code: **CAC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210862/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Mar 23, 2021
Decision date	Jul 29, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sisu Global Health</b>
Location	Baltimore, MD, US
Contact	Gillian Henker
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>in2being, LLC</b>
Contact	Adrienne Harris

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/k210862/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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