

**K230273 Saranas Early Bird Bleed Monitoring System**May 25, 2023  
114 days to decisionK230273 · Product code: **QFJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230273/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravascular Bleed Monitor (QFJ)
Date received	Jan 31, 2023
Decision date	May 25, 2023
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Saranas, Inc.</b>
Location	Houston, TX, US
Contact	Odell Roberts
510(k) history	2 submissions · 1 cleared · 2019-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Allison Komiyama

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/k230273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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