

**K230310 STAT Medical Device Lancing System**Sep 8, 2023  
217 days to decisionK230310 · Product code: **QRK** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k230310/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Feb 3, 2023
Decision date	Sep 8, 2023
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stat Medical Devices</b>
Location	North Miami Beach, FL, US
Contact	Hemel Mariano
510(k) history	3 submissions · 3 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>FDA Compliance Group</b>
Contact	Kevin Walls

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230310/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026