

K223815 ONE DROP Lancing DeviceFeb 15, 2023
57 days to decisionK223815 · Product code: **QRK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Dec 20, 2022
Decision date	Feb 15, 2023
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	FDA Compliance Group
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.netDevice record: <https://www.510kdatabase.net/k223815/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026