

K221175 Multi-Lancet Device 2, ReliOn Premier Lancing DeviceOct 17, 2022
175 days to decisionK221175 · Product code: **QRL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Apr 25, 2022
Decision date	Oct 17, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arkray, Inc.
Location	Beverly, MA, US
Contact	Shinjiro Sekimoto
510(k) history	18 submissions · 18 cleared · 2002-2024

REGULATORY CONSULTANT

Consulting firm	Arkray Factory USA, Inc.
Contact	Joe Dempsey

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/k221175/> 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