

K250813 MICROLET®NEXT 2 Lancing DeviceMay 14, 2025
58 days to decisionK250813 · Product code: **QRL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Mar 17, 2025
Decision date	May 14, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ascensia Diabetes Care U.S., Inc.
Location	Mishawaka, IN, US
Contact	Sangram Yadav
510(k) history	7 submissions · 7 cleared · 2016-2025

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