

K241810 MICROLET®NEXT LancetAug 15, 2024
55 days to decisionK241810 · Product code: **QRK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241810/>**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	Jun 21, 2024
Decision date	Aug 15, 2024
Days to decision	55 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241810/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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