

K220364 Accu-Chek Safe-T-Pro Uno Lancing DeviceApr 5, 2022
56 days to decisionK220364 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Feb 8, 2022
Decision date	Apr 5, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diabetes Care, Inc.
Location	Indianapolis,, IN, US
Contact	Julia Best
510(k) history	9 submissions · 9 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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