FDA 510(k) Premarket Notification

K220364 Accu-Chek Safe-T-Pro Uno Lancing Device

CLEARED

Apr 5, 2022
56 days to decision

K220364 · Product code: **FMK** · General & Plastic Surgery
Source: 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