FDA 510(k) Premarket Notification

CLEARED

K220849 Accu-Chek Safe-T-Pro Plus Lancing Device

May 19, 2022
57 days to decision

K220849 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220849/

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	Mar 23, 2022
Decision date	May 19, 2022
Days to decision	57 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	Jason Lee
510(k) history	9 submissions · 9 cleared · 2015-2023