FDA 510(k) Premarket Notification

K223352 Tenderfoot

CLEARED

Mar 2, 2023
120 days to decision

K223352 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Nov 2, 2022
Decision date	Mar 2, 2023
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Accriva Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	Wenni Haley
510(k) history	3 submissions · 3 cleared · 2019-2023