FDA 510(k) Premarket Notification

CLEARED

K222084 OneTouch Delica Safety, HemoCue Safety Lancet, Assure Lance and Assure Lance Plus, Capiject Safety Lancet, Heel Lancet Newborn, Heel Lancet Preemie

Nov 2, 2022
110 days to decision

K222084 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222084/

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	Jul 15, 2022
Decision date	Nov 2, 2022
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Asahi Polyslider Co., Ltd.**
Location	Maniwa, JP
Contact	Yoshitaka Akagi
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Emergo by UL**
Contact	Stuart R Goldman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov