FDA 510(k) Premarket Notification

K223826 NanoDrop Lancet

CLEARED

Feb 22, 2024
428 days to decision

K223826 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223826/

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	Dec 21, 2022
Decision date	Feb 22, 2024
Days to decision	428 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Drawbridge Health, Inc.**
Location	San Diego, CA, US
Contact	Dan McEvoy
510(k) history	2 submissions · 2 cleared · 2019-2024