FDA 510(k) Premarket Notification

K234081 RedDrop ONE (One)

CLEARED

Mar 21, 2024
90 days to decision

K234081 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k234081/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Dec 22, 2023
Decision date	Mar 21, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Reddrop DX**
Location	Fort Collins, CO, US
Contact	Kris Buchanan
510(k) history	1 submissions · 0 cleared · 2024-2024