FDA 510(k) Premarket Notification

K223480 Medipoint Blood Lancets

CLEARED

Jan 13, 2023
56 days to decision

K223480 · Product code: **QRK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Nov 18, 2022
Decision date	Jan 13, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medipoint Holdings, LLC**
Location	Mineola, NY, US
Contact	Rochelle Stern
510(k) history	1 submissions · 1 cleared · 2023-2023