FDA 510(k) Premarket Notification

K230310 STAT Medical Device Lancing System

CLEARED

Sep 8, 2023
217 days to decision

K230310 · Product code: **QRK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230310/

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	Feb 3, 2023
Decision date	Sep 8, 2023
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stat Medical Devices**
Location	North Miami Beach, FL, US
Contact	Hemel Mariano
510(k) history	3 submissions · 3 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**FDA Compliance Group**
Contact	Kevin Walls

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