

K222617 EasyTouch Lancing DeviceMar 21, 2023
203 days to decisionK222617 · Product code: **QRK** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k222617/>**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	Aug 30, 2022
Decision date	Mar 21, 2023
Days to decision	203 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026