FDA 510(k) Premarket Notification

K221175 Multi-Lancet Device 2, ReliOn Premier Lancing Device

CLEARED

Oct 17, 2022
175 days to decision

K221175 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Apr 25, 2022
Decision date	Oct 17, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arkray, Inc.**
Location	Beverly, MA, US
Contact	Shinjiro Sekimoto
510(k) history	18 submissions · 18 cleared · 2002-2024

REGULATORY CONSULTANT

Consulting firm	**Arkray Factory USA, Inc.**
Contact	Joe Dempsey

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