FDA 510(k) Premarket Notification

CLEARED

K221062 RIGHTEST Lancing Device GD500, GE Lancing Device, iGlucose Lancing Device

Sep 26, 2022
168 days to decision

K221062 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Apr 11, 2022
Decision date	Sep 26, 2022
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bionime Corporation**
Location	Great Neck, NY, US
Contact	Yu Chi Huang
510(k) history	21 submissions · 21 cleared · 2005-2024

REGULATORY CONSULTANT

Consulting firm	**Symbiosis Consulting , Ltd.**
Contact	I Hsin Li

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