FDA 510(k) Premarket Notification

CLEARED

K231797 Medifun Lancing Device, Model No. LD-E1

Nov 22, 2023
155 days to decision

K231797 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231797/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Jun 20, 2023
Decision date	Nov 22, 2023
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medifun Corporation**
Location	Taichung City, TW
Contact	Aaron Chen
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Voler Biotech Consulting CO., Ltd.**
Contact	Tyra Chiu

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