

K231797 Medifun Lancing Device, Model No. LD-E1Nov 22, 2023
155 days to decisionK231797 · Product code: **QRL** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231797/> 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 25, 2026