FDA 510(k) Premarket Notification

CLEARED

K241750 Medifun Safety Lancet (MSL1 series)

Aug 15, 2024
58 days to decision

K241750 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Jun 18, 2024
Decision date	Aug 15, 2024
Days to decision	58 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	Mandy Lin

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