FDA 510(k) Premarket Notification

K210567 Ultrasonic Surgical System

CLEARED

Sep 30, 2022
581 days to decision

K210567 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Feb 26, 2021
Decision date	Sep 30, 2022
Days to decision	581 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Miconvey Technologies Co., Ltd.**
Location	Chongqing, CN
Contact	Kang Li
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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