FDA 510(k) Premarket Notification

K232721 Lifetech Cardio Temporary Pacemaker

CLEARED

Jan 7, 2024
124 days to decision

K232721 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k232721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Sep 5, 2023
Decision date	Jan 7, 2024
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Lifetech Cardio Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Stephy Pan
510(k) history	2 submissions · 2 cleared · 2019-2024