

K232721 Lifetech Cardio Temporary PacemakerJan 7, 2024
124 days to decisionK232721 · 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232721/> 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 13, 2026