

**K232261 TME Temporary Myocardial Electrode**Apr 26, 2024  
270 days to decisionK232261 · Product code: **LDF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k232261/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Jul 31, 2023
Decision date	Apr 26, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osypka AG</b>
Location	Rheinfelden, DE
Contact	Nicola Osypka
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232261/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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