

K200849 Tempus LS - ManualJul 24, 2020
115 days to decisionK200849 · Product code: **LDD** · Cardiovascular
Source: <https://www.510kdatabase.net/k200849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Mar 31, 2020
Decision date	Jul 24, 2020
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Remote Diagnostic Technologies, Ltd. A Philips Company
Location	Basingstoke, GB
Contact	Martin Newman
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Nsf Health Sciences, LLC
Contact	Meaghan Bailey

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200849/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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