

K221141 PageWriter TC35 CardiographDec 2, 2022
227 days to decisionK221141 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k221141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Apr 19, 2022
Decision date	Dec 2, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medizin Systeme Boblingen GmbH
Location	Boblingen, DE
Contact	Judy Yang
510(k) history	1 submissions · 1 cleared · 2022-2022

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