

K200884 B-Secur HeartKey Software LibraryDec 7, 2020
249 days to decisionK200884 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k200884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Apr 2, 2020
Decision date	Dec 7, 2020
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B-Secur , Ltd.
Location	Belfast, GB
Contact	David Brown
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	B-Secur Ltd. C/O Promedic, LLC
Contact	Paul Dryden

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

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