

K220786 STAR Apollo Mapping SystemDec 1, 2022
259 days to decisionK220786 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k220786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 17, 2022
Decision date	Dec 1, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rhythm AI, Ltd.
Location	Witney, GB
Contact	Linda D'Abate
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Rhythm-AI
Contact	Linda D'Abate

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

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