

**K230386 SpassageQ**Jun 15, 2023  
121 days to decisionK230386 · Product code: **PLB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230386/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multivariate Vital Signs Index (PLB)
Date received	Feb 14, 2023
Decision date	Jun 15, 2023
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spass, Inc.</b>
Location	Seoul, KR
Contact	Yonghwan Kim
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Radios, LLC</b>
Contact	Edward Park

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

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