

K241101 BioButton SystemSep 26, 2024
157 days to decisionK241101 · Product code: **DRG** · CardiovascularSource: <https://www.510kdatabase.net/k241101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Apr 22, 2024
Decision date	Sep 26, 2024
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biointellisense, Inc.
Location	Redwood City, CA, US
Contact	Yusi Liu
510(k) history	2 submissions · 2 cleared · 2019-2024

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