

K212957 BioButton SystemDec 12, 2022
452 days to decisionK212957 · Product code: **DRG** · CardiovascularSource: <https://www.510kdatabase.net/k212957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Sep 16, 2021
Decision date	Dec 12, 2022
Days to decision	452 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	1 submissions · 1 cleared · 2022-2022

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