

K191614 BioSticker SystemDec 18, 2019
183 days to decisionK191614 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k191614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Jun 18, 2019
Decision date	Dec 18, 2019
Days to decision	183 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191614/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026