

K180479 ReDS SystemFeb 28, 2019
371 days to decisionK180479 · Product code: **DSB** · Cardiovascular
Source: <https://www.510kdatabase.net/k180479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Feb 22, 2018
Decision date	Feb 28, 2019
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sensible Medical Innovations , Ltd.
Location	Netanya, IL
Contact	Inbal Ben-Tzvi
510(k) history	2 submissions · 2 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180479/> 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 June 28, 2026