FDA 510(k) Premarket Notification

K180479 ReDS System

CLEARED

Feb 28, 2019
371 days to decision

K180479 · 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