FDA 510(k) Premarket Notification

CLEARED

K182196 Cardiart Electronic Stethoscope Model DS101 Omni-Steth Electronic Stethoscope Model Omni-Steth

Sep 11, 2018
28 days to decision

K182196 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k182196/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Aug 14, 2018
Decision date	Sep 11, 2018
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imediplus, Inc.**
Location	Chubei City, TW
Contact	Moriah Hsieh
510(k) history	3 submissions · 3 cleared · 2016-2018

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov