

**K182196 Cardiart Electronic Stethoscope Model DS101 Omni-Steth Electronic Stethoscope Model Omni-Steth**Sep 11, 2018  
28 days to decisionK182196 · Product code: **DQD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182196/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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

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