

K182905 UniPulseDec 14, 2018
59 days to decisionK182905 · Product code: **DRL** · Cardiovascular
Source: <https://www.510kdatabase.net/k182905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Defibrillator (DRL)
Date received	Oct 16, 2018
Decision date	Dec 14, 2018
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Seaward Group
Location	Peterlee, GB
Contact	Jim Wallace
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Steurer Consulting Group
Contact	Robert Steurer

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182905/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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