FDA 510(k) Premarket Notification

K182905 UniPulse

CLEARED

Dec 14, 2018
59 days to decision

K182905 · 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