FDA 510(k) Premarket Notification

K190437 Delta 3300

CLEARED

Aug 28, 2019
187 days to decision

K190437 · Product code: **DRL** · Cardiovascular
Source: https://www.510kdatabase.net/k190437/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Defibrillator (DRL)
Date received	Feb 22, 2019
Decision date	Aug 28, 2019
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Netech Corporation**
Location	Farmingdale, NY, US
Contact	Mohan Das
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Brij Strategic Consultations, LLC**
Contact	Mukesh Kumar

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