FDA 510(k) Premarket Notification

K180366 EndoTool SubQ

CLEARED

Sep 20, 2018
220 days to decision

K180366 · Product code: **NDC** · General Hospital
Source: https://www.510kdatabase.net/k180366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Feb 12, 2018
Decision date	Sep 20, 2018
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Al Pacheco and Associates**
Location	Carlsbad, CA, US
Contact	Al Pacheco
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Certified Compliance Solutions**
Contact	Al Pacheco

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