

**K180366 EndoTool SubQ**Sep 20, 2018  
220 days to decisionK180366 · Product code: **NDC** · General Hospital  
Source: <https://www.510kdatabase.net/k180366/>**SUBMISSION DETAILS**

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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**

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Company	<b>AI Pacheco and Associates</b>
Location	Carlsbad, CA, US
Contact	AI Pacheco
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Certified Compliance Solutions</b>
Contact	AI Pacheco

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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