

K211160 EndoTool SubQ 2.1Oct 28, 2021
192 days to decisionK211160 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k211160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Apr 19, 2021
Decision date	Oct 28, 2021
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Monarch Medical Technologies, LLC
Location	Charlotte, NC, US
Contact	Ann Marie Gaitan
510(k) history	3 submissions · 3 cleared · 2020-2021

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