

K200443 EndoTool IV 1.10Mar 17, 2020
22 days to decisionK200443 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k200443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Feb 24, 2020
Decision date	Mar 17, 2020
Days to decision	22 days
Third-party review	Yes
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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