

**K201619 EndoTool IV System**Aug 7, 2020  
53 days to decisionK201619 · Product code: **NDC** · Chemistry  
Source: <https://www.510kdatabase.net/k201619/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Jun 15, 2020
Decision date	Aug 7, 2020
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026