

**K200646 TubeClear System**Dec 4, 2020  
267 days to decisionK200646 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k200646/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Mar 12, 2020
Decision date	Dec 4, 2020
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Actuated Medical, Inc.</b>
Location	Bellefonte, PA, US
Contact	Michael T. Britton
510(k) history	10 submissions · 10 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200646/> 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 25, 2026