

**K212728 Standard Bougie, 38 Fr. and Hand Pump**Sep 23, 2021  
27 days to decisionK212728 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212728/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Aug 27, 2021
Decision date	Sep 23, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Standard Bariatrics</b>
Location	Cincinnati, OH, US
Contact	Michelle Schnell
510(k) history	10 submissions · 10 cleared · 2016-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212728/> 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