

K210437 Standard Bougie, 38 Fr.Jun 29, 2021
137 days to decisionK210437 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Feb 12, 2021
Decision date	Jun 29, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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