

K222085 Standard Tapered Bougie, 38 Fr.Oct 31, 2022
108 days to decisionK222085 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Jul 15, 2022
Decision date	Oct 31, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Standard Bariatrics, Inc.
Location	Cincinnati, OH, US
Contact	Michelle Schnell
510(k) history	2 submissions · 2 cleared · 2022-2023

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