

K191885 Standard BougieApr 8, 2020
268 days to decisionK191885 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Jul 15, 2019
Decision date	Apr 8, 2020
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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