

**K191340 CORTRAK\* 2 Equilateral Enteral Access System**Jun 4, 2019  
15 days to decisionK191340 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k191340/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	May 20, 2019
Decision date	Jun 4, 2019
Days to decision	15 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avanos Medical, Inc.</b>
Location	Alpharetta, GA, US
Contact	Monica King
510(k) history	8 submissions · 8 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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