

K193325 Avantgarde Faecal Management Systems, Avantgarde Faecal Management System Replacement PouchesMar 13, 2020
102 days to decisionK193325 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k193325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 2, 2019
Decision date	Mar 13, 2020
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prosys International, Ltd.
Location	Wimbledon, GB
Contact	Graham Steer
510(k) history	1 submissions · 1 cleared · 2020-2020

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