

K252140 Heylo™ SystemOct 6, 2025
90 days to decisionK252140 · Product code: **EXB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Ostomy (EXB)
Date received	Jul 8, 2025
Decision date	Oct 6, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	Preeti Jain
510(k) history	54 submissions · 47 cleared · 1985-2025

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