

K201007 In-Ka Ureteral Balloon Dilatation CatheterJun 11, 2020
55 days to decisionK201007 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Apr 17, 2020
Decision date	Jun 11, 2020
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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