

**K201165 In-Ka Percutaneous Balloon Dilatation Catheters,
Amplatz Sheath**Dec 17, 2020
230 days to decisionK201165 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	May 1, 2020
Decision date	Dec 17, 2020
Days to decision	230 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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