

**K924406 CONVEEN(R) LEG BAG(500 ML)**Oct 30, 1992  
66 days to decisionK924406 · Product code: **FAQ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k924406/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bag, Urine Collection, Leg, For External Use, Sterile (FAQ)
Date received	Aug 25, 1992
Decision date	Oct 30, 1992
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Coloplast A/S</b>
Location	Mchenry, IL, US
Contact	RICHARD A HAMER
Website	<a href="http://www.coloplast.com/">http://www.coloplast.com/</a>
510(k) history	71 submissions · 68 cleared · 1983-2023

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...

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