

K953767 PROSYS BEDSIDE DRAINAGE BAGDec 20, 1995
131 days to decisionK953767 · Product code: **FAQ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k953767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bag, Urine Collection, Leg, For External Use, Sterile (FAQ)
Date received	Aug 11, 1995
Decision date	Dec 20, 1995
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Convatec, A Division of E.R. Squibb & Sons
Location	Walker, MI, US
Contact	SUSIE AMBERGER
510(k) history	81 submissions · 68 cleared · 1982-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953767/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 1, 2026