

K973364 4L DRAINAGE BAG, 4L BAG FOR PERITONEAL DIALYSIS, 4L URINARY DRAINAGE BAG

Mar 17, 1998
190 days to decision

K973364 · Product code: **KNX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k973364/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Sep 8, 1997
Decision date	Mar 17, 1998
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maersk Medical A/S
Location	Sylmar, CA, US
Contact	JOERGEN M NIELSEN
510(k) history	9 submissions · 9 cleared · 1998-2001

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Device record: <https://www.510kdatabase.net/k973364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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