

K951443 STANDARD FOLEY SYSTEM PAKJun 15, 1995
78 days to decisionK951443 · Product code: **FCN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k951443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Drainage Collection Kit, For Indwelling Catheter (FCN)
Date received	Mar 29, 1995
Decision date	Jun 15, 1995
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trinity Laboratories, Inc.
Location	Raleigh, NC, US
Contact	PARTHA BASUMALLIK
510(k) history	44 submissions · 28 cleared · 1990-1998

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