

K950344 HORIZON FOLEY CATHETERIZATION TRAY WITHOUT CATHETERMar 24, 1995
56 days to decisionK950344 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k950344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Jan 27, 1995
Decision date	Mar 24, 1995
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acacia Laboratories, Inc.
Location	Santa Ana, CA, US
Contact	BEN WALTHALL
510(k) history	12 submissions · 10 cleared · 1988-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950344/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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