

K923538 MON-A-THERM FOLEY KITMay 27, 1993
315 days to decisionK923538 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k923538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Jul 16, 1992
Decision date	May 27, 1993
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mallinckrodt Medical
Location	St Louis, MO, US
Contact	JEFFERY W BIGGERS
510(k) history	43 submissions · 42 cleared · 1990-2008

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