

K971627 SILICONE ANTIBACTERIAL FOLEY CATHETERJan 13, 1998
256 days to decisionK971627 · Product code: **MJC** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (antimicrobial) And Accessories (MJC)
Date received	May 2, 1997
Decision date	Jan 13, 1998
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rochester Medical Corp.
Location	Rochester, MN, US
Contact	RICHARD D FRYAR
510(k) history	13 submissions · 13 cleared · 1990-2013

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