

K970704 PERSONAL CATHETERMar 13, 1997
15 days to decisionK970704 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Feb 26, 1997
Decision date	Mar 13, 1997
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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