

K041416 EXAC-TEMP FOLEY CATHETER AND CLINI-TEMP FOLEY CATHETERJul 2, 2004
36 days to decisionK041416 · Product code: EYC · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k041416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Upper Urinary Tract (EYC)
Date received	May 27, 2004
Decision date	Jul 2, 2004
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Deroyal
Location	Knoxville, TN, US
Contact	SHARON COOK
Website	http://www.deroyal.com/
510(k) history	5 submissions · 5 cleared · 2002-2004

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