

**K013597 TAMPONADE UTERINE BALLOON CATHETER SET**Apr 17, 2002  
168 days to decisionK013597 · Product code: **KNA** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k013597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Specialized Obstetric-gynecologic (KNA)
Date received	Oct 31, 2001
Decision date	Apr 17, 2002
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ob/Gyn</b>
Location	Bloomington, IN, US
Contact	CINDY RUMPLE
510(k) history	43 submissions · 43 cleared · 1985-2006

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