

K062438 BAKRI POSTPARTUM BALLOON, MODEL J-SOS-100500

Oct 27, 2006
67 days to decision

K062438 · Product code: **KNA** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k062438/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Specialized Obstetric-gynecologic (KNA)
Date received	Aug 21, 2006
Decision date	Oct 27, 2006
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k062438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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