FDA 510(k) Premarket Notification

K113686 KIMONO MICROTHIN WITH AQUA LUBE, REALITY ULTRA LUBRICATED

CLEARED

Mar 6, 2012
82 days to decision

K113686 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k113686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Dec 15, 2011
Decision date	Mar 6, 2012
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mayer Laboratories, Inc.**
Location	Berkely, CA, US
Contact	DAVID P MAYER
510(k) history	3 submissions · 3 cleared · 2011-2013