FDA 510(k) Premarket Notification

K123330 IOGYN ENDOSCOPE

CLEARED

Mar 19, 2013
144 days to decision

K123330 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k123330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 26, 2012
Decision date	Mar 19, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iogyn, Inc.**
Location	Minneapolis, MN, US
Contact	Mary J Edwards
510(k) history	3 submissions · 2 cleared · 2013-2014