FDA 510(k) Premarket Notification

K110612 FM20

CLEARED

Nov 8, 2011
250 days to decision

K110612 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k110612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 3, 2011
Decision date	Nov 8, 2011
Days to decision	250 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Mediana Co., Ltd.**
Location	Flintville, TN, US
Contact	AMY KIM
510(k) history	10 submissions · 10 cleared · 2005-2020