FDA 510(k) Premarket Notification

K131941 FETAL MONITORS

CLEARED

May 15, 2014
322 days to decision

K131941 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k131941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jun 27, 2013
Decision date	May 15, 2014
Days to decision	322 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guangdong Biolight Meditech Co., Ltd.**
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	21 submissions · 21 cleared · 2008-2019