

K131941 FETAL MONITORSMay 15, 2014
322 days to decisionK131941 · Product code: **HGM** · Obstetrics & GynecologySource: <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

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