

K140163 KOALA TOCOMay 29, 2014
127 days to decisionK140163 · Product code: **HFM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k140163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Uterine Contraction, External (for Use In Clinic) (HFM)
Date received	Jan 22, 2014
Decision date	May 29, 2014
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Innovations, LLC
Location	Murray, UT, US
Contact	JOANNE BRONIKOWSKI
510(k) history	9 submissions · 9 cleared · 2007-2025

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