FDA 510(k) Premarket Notification

K102140 FETAL MONITORS, MODELS F2 AND F3

CLEARED

Jan 13, 2011
168 days to decision

K102140 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k102140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 29, 2010
Decision date	Jan 13, 2011
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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510(k) history	92 submissions · 92 cleared · 2004-2026