FDA 510(k) Premarket Notification

K161902 Meridian M110 Fetal Monitoring System

CLEARED

Jan 12, 2017
185 days to decision

K161902 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k161902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 11, 2016
Decision date	Jan 12, 2017
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mindchild Medical**
Location	Providence, RI, US
Contact	JIM ROBERTSON
510(k) history	3 submissions · 3 cleared · 2012-2017