FDA 510(k) Premarket Notification

K173941 IntelliSpace Perinatal Rev.K.00

CLEARED

Sep 10, 2018
258 days to decision

K173941 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k173941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Dec 26, 2017
Decision date	Sep 10, 2018
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medizin Systeme Boeblingen GmbH**
Location	B?blingen, DE
Contact	Christoph Krause
510(k) history	48 submissions · 48 cleared · 2004-2026