FDA 510(k) Premarket Notification

K062137 MODIFICATION TO PHILIPS AVALON FETAL MONITORS FM20 AND FM30

CLEARED

Aug 24, 2006
29 days to decision

K062137 · Product code: **HGM** · Radiology
Source: https://www.510kdatabase.net/k062137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 26, 2006
Decision date	Aug 24, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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