FDA 510(k) Premarket Notification

K241368 Sonicaid Team3

CLEARED

Feb 3, 2025
265 days to decision

K241368 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k241368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	May 14, 2024
Decision date	Feb 3, 2025
Days to decision	265 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Huntleigh Healthcare , Ltd.**
Location	Cardiff, GB
Contact	Steve Monks
Website	http://www.huntleigh-diagnostics.com/diagnostics/uk/
510(k) history	8 submissions · 8 cleared · 2006-2025

Huntleigh Healthcare, Ltd. is a leading global provider of innovative medical devices for vascular assessment and treatment, fetal monitoring, and patient monitoring. A proud member of the Arjo family, the company operates with a manufacturing facility in Cardiff, United Kingdom, and serves healthcare professionals across more than 100 countries with over 40 years of clinical expertise. The company has received FDA 510(k) clearances from total submissions since 2006, with no denied submissions. Huntleigh's cleared devices span Obstetrics & Gynecology, Cardiovascular, and ...

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k241368/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026