

K250777 Sonicaid Team3Sep 19, 2025
189 days to decisionK250777 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 14, 2025
Decision date	Sep 19, 2025
Days to decision	189 days
Third-party review	No
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 ...

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Device record: <https://www.510kdatabase.net/k250777/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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