FDA 510(k) Premarket Notification

K090285 SONICAID FM820 AND FM830 ENCORE

CLEARED

Jul 15, 2009
160 days to decision

K090285 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k090285/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Feb 5, 2009
Decision date	Jul 15, 2009
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Huntleigh Healthcare , Ltd.**
Location	Cardiff, GB
Contact	GRAHAM BOOTH
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 ...