FDA 510(k) Premarket Notification

K002150 SONICAID FM820, SONICAID FM830

CLEARED

Mar 9, 2001
235 days to decision

K002150 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k002150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 17, 2000
Decision date	Mar 9, 2001
Days to decision	235 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Oxford Instruments**
Location	Old Woking, Surrey, GB
Contact	STEVE VALE
510(k) history	2 submissions · 2 cleared · 2000-2001