

K101801 MONICA AN24Feb 3, 2011
220 days to decisionK101801 · Product code: **OSP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k101801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Uterine Electromyographic Monitor (OSP)
Date received	Jun 28, 2010
Decision date	Feb 3, 2011
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Monica Healthcare
Location	Nottingham, GB
Contact	IAN HOW
510(k) history	2 submissions · 2 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101801/> 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 June 18, 2026