

**K112390 MONICA AN24**Jul 13, 2012  
330 days to decisionK112390 · Product code: **OSP** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k112390/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Uterine Electromyographic Monitor (OSP)
Date received	Aug 18, 2011
Decision date	Jul 13, 2012
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Monica Healthcare, Ltd.</b>
Location	Nottingham, GB
Contact	IAN HOW
510(k) history	2 submissions · 2 cleared · 2012-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112390/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 6, 2026