

**K791038 FETASONDE UTERINE ACTIVITY MONITOR**Sep 4, 1979  
91 days to decisionK791038 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k791038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jun 5, 1979
Decision date	Sep 4, 1979
Days to decision	91 days
Third-party review	No

**APPLICANT**

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Company	<b>Roche Medical Electronics, Inc.</b>
Location	Mchenry, IL, US
510(k) history	16 submissions · 16 cleared · 1976-1979

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k791038/> 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 May 28, 2026