

K791039 FETASONDE FETAL HEART RATE VARIABILITYSep 4, 1979
91 days to decisionK791039 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k791039/>**SUBMISSION DETAILS**

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

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

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Device record: <https://www.510kdatabase.net/k791039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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