FDA 510(k) Premarket Notification

K791038 FETASONDE UTERINE ACTIVITY MONITOR

CLEARED

Sep 4, 1979
91 days to decision

K791038 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k791038/

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