FDA 510(k) Premarket Notification

K831852 FETAL MONITOR #115

CLEARED

Aug 11, 1983
63 days to decision

K831852 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k831852/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jun 9, 1983
Decision date	Aug 11, 1983
Days to decision	63 days
Third-party review	No

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
510(k) history	136 submissions · 132 cleared · 1978-2012