FDA 510(k) Premarket Notification

K894030 MODEL 37 UTERINE CONTRACTION ACTIVITY MONITOR

CLEARED

Jan 22, 1990
230 days to decision

K894030 · Product code: **HFM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k894030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Uterine Contraction, External (for Use In Clinic) (HFM)
Date received	Jun 6, 1989
Decision date	Jan 22, 1990
Days to decision	230 days
Third-party review	No

APPLICANT

Company	**Healthdyne, Inc.**
Location	Mchenry, IL, US
Contact	TIM COWART
510(k) history	35 submissions · 35 cleared · 1978-1995