FDA 510(k) Premarket Notification

K020390 MODIFICATION TO FETAL ASSIST

CLEARED

Apr 19, 2002
72 days to decision

K020390 · Product code: **LQK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k020390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Home Uterine Activity Monitor (LQK)
Date received	Feb 6, 2002
Decision date	Apr 19, 2002
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Huntleigh Diagnostics , Ltd.**
Location	Cardiff Wales, GB
Contact	AUDREY WITKO
510(k) history	3 submissions · 3 cleared · 2000-2002