FDA 510(k) Premarket Notification

K130002 SURECALL LABOR MONITOR

CLEARED

Jun 28, 2013
177 days to decision

K130002 · Product code: **OSP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k130002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Uterine Electromyographic Monitor (OSP)
Date received	Jan 2, 2013
Decision date	Jun 28, 2013
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Reproductive Research Technologies, LP**
Location	Houston, TX, US
Contact	J. HARVEY KNAUSS
510(k) history	2 submissions · 2 cleared · 2011-2013