

K131889 EUM 100PROApr 23, 2014
302 days to decisionK131889 · Product code: **OSP** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k131889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Uterine Electromyographic Monitor (OSP)
Date received	Jun 25, 2013
Decision date	Apr 23, 2014
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Promedic, Inc.
Location	Indianapolis, IN, US
Contact	PAUL DRYDEN
510(k) history	16 submissions · 14 cleared · 1995-2014

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