

K231964 Novii+ Wireless Patch SystemDec 8, 2023
158 days to decisionK231964 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k231964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 3, 2023
Decision date	Dec 8, 2023
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Datex-Ohmeda
Location	Tewksbury, MA, US
Contact	Isabel McGann
510(k) history	41 submissions · 41 cleared · 2000-2023

CLINICAL EVIDENCE - NCT03057275

Performance of the Monica Novii Wireless Patch System in Pre-term Labor

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	47 patients (actual)
Study sites	1 site
Condition studied	Premature Labor
Study type	Observational
Completion date	Sep 20, 2019
Sponsor	GE Healthcare (Industry)

Primary outcome**FHR Percent Agreement**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03057275510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231964/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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