

K243291 Goldtrace Fetal Spiral Electrode (FSE) (CNS000004)Jan 17, 2025
91 days to decisionK243291 · Product code: **HGP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Circular (spiral), Scalp And Applicator (HGP)
Date received	Oct 18, 2024
Decision date	Jan 17, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neovanta Medical AB
Location	M?indal, SE
Contact	Johan Sundberg
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243291/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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