January 17, 2025

Neoventa Medical AB
Johan Sundberg
Chief Quality and Regulatory Officer
Norra Ågatan 32
Mölndal, Västra Götaland SE-431 35
SWEDEN

Re: K243291
Trade/Device Name: Goldtrace Fetal Spiral Electrode (FSE) (CNS000004)
Regulation Number: 21 CFR 884.2675
Regulation Name: Fetal Scalp Circular (Spiral) Electrode and Applicator
Regulatory Class: II
Product Code: HGP
Dated: October 18, 2024
Received: October 18, 2024

Dear Johan Sundberg:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K243291

Device Name
Goldtrace Fetal Spiral Electrode (FSE) (CNS000004)

Indications for Use *(Describe)*
Goldtrace FSE is indicated for patients requiring continuous electronic intrapartum monitoring of the fetal heart rate during labor and delivery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary – Goldtrace Fetal Spiral Electrode (K243291)

## I. SUBMITTER

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Date Summary Prepared: January 17, 2025

Contact Person:
Johan Sundberg
Chief Quality and Regulatory Officer
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## II. DEVICE

Device Trade Name: Goldtrace Fetal Spiral Electrode (Goldtrace FSE), CNS000004
Device Common Name: Fetal Spiral Electrode (FSE)
Regulation number: 21 CFR 884.2675
Regulation Name: Fetal scalp circular (spiral) electrode and applicator
Regulatory Class: II
Product code: HGP (electrode, circular (spiral), scalp and applicator)
Classification Panel: Obstetrics/Gynecology

## III. PREDICATE DEVICE

Device Name: Fetal Spiral Electrode
Manufacturer: Clinical Innovations, Inc
510(k) Number: K030691

The predicate device has not been subject to a design-related recall.

## IV. DEVICE DESCRIPTION

Goldtrace FSE is a sterile, single use device transmitting the fetal ECG signal for continuous electronic intrapartum monitoring.

The Goldtrace FSE is intended for use in fetuses and mothers after rupture of the amniotic membranes requiring continuous electronic intrapartum monitoring of the fetal heart rate or analysis of the fetal ECG waveform. Goldtrace FSE is intended to be used by medically trained personnel at delivery wards.

The device consists of gold-plated stainless steel spiral needle electrode that attaches to the fetal presenting part. The device includes a reference plate to measure the reference voltage level in the amniotic fluid. A guide tube and drive tube are used for application to the fetal presenting part. The subject device is connected to a compatible monitor (e.g., Philips Avalon FM30) via Philips DECG Reusable Legplate adaptor cable to provide a fetal ECG signal to the monitor. The subject device does not perform any conversion, analysis, quantification, or modifications to the fetal ECG.

The Goldtrace FSE materials conform to FDA recognized consensus standard for medical use (ISO 10993-1: 2018) and the device is sterilized using Ethylene Oxide sterilization (EO).

## V. INDICATIONS FOR USE

Goldtrace FSE is indicated for patients requiring continuous electronic intrapartum monitoring of the fetal heart rate during labor and delivery.

## VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device and predicate device are intended to be used on patients during labor requiring electronic intrapartum monitoring of the fetal heart rate by means of a spiral electrode.

Following table provides comparison of the intended use and technological characteristics of the subject device with the predicate device:

| **Specification** | Subject Device (K243291) | Predicate Device (K030691) |
|---|---|---|
| **Intended Use** | Goldtrace FSE is indicated for patients requiring continuous electronic intrapartum monitoring of the fetal heart rate during labor and delivery. | For patients requiring fetal heart rate monitoring during labor. |
| **Principle of Operation** | Transmit fetal ECG signal for recording, analysis and quantification of the monitor | Transmit fetal ECG signal for recording, analysis, and quantification of the monitor |
| **Electrode Design** | Single spiral needle with twisted two-wire concept. Guide tube and drive tube used for application. | Single spiral needle with twisted two-wire concept. Guide tube and drive tube used for application. |
| **FSE components** | Spiral needle, Reference Plate, Connector, Guide Tube, Drive Tube, Drive Tube Grip, Wires | Spiral needle, Reference Plate, Connector, Guide Tube, Drive Tube, Drive Tube Grip, Wires |
| **Materials used for spiral electrode** | SS316 stainless steel for electrodes with 10-25 µm gold-plated surface | Stainless steel for electrodes |
| **Spiral needle diameter** | Diameter: 4.7mm (0.185 inches) ± 0.13mm (0.005 inches) (O.D.) Outside Diameter: 0.55 mm (0.021 inches) ± 0.05 mm (0.002 inches) | Not publicly available |
| **Hub** | Outside diameter: 0.219 inches ± 005 inches (O.D.) | Not publicly available |
| **Wires** | Length: 60 cm (23.6 inches) ± 2 cm (0.8 inches) | Not publicly available |

| | | |
|---|---|---|
| **Shelf life** | 5 years | Not publicly available |
| **Sterile** | Yes | Yes |
| **Single use** | Yes | Yes |

The subject and predicate device have similar indications for use statements and have the same intended use – continuous intrapartum monitoring of fetal ECG. The subject device (Goldtrace Fetal Spiral Electrode) has similar fundamental scientific technology to the predicate device (Fetal Scalp Electrode). The subject device differs from the predicate device in terms of device materials, dimensions, and electrical properties. The different technological features of the subject device do not raise different questions of safety and effectiveness as compared to the predicate device.

## VII. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

Biological evaluation of the subject device has been performed in accordance with the 2024 FDA guidance "*Use of International standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*" as well as ISO 10993- 1:2018 "*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*". Biocompatibility of the subject device is supported by performed tests of the following biological endpoints:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Systemic Toxicity (ISO 10993-11:2006)
- Material Mediated Pyrogenicity (USP38-NF33:2015 <151> Pyrogen Test)

The subject device was found to be non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, and non-pyrogenic (material mediated).

Electrical Safety and Electromagnetic Compatibility

Testing was conducted in accordance with IEC 60601- 1:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, and IEC 60601-1-2:2014 + AMD:2020, *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*, to support the electrical safety and electromagnetic compatibility of the subject device. Device was also tested (with deviations consistent with the device's intended use) according ANSI/AAMI EC12 EC12:2000/(R)2015 - *Disposable ECG electrodes* and ANSI/AAMI EC53 2013/(R)2020 - *ECG trunk cables and patient leadwires*.

Sterility and Shelf-Life

Following testing was conducted to support sterility and shelf-life of the subject device:

- Ethylene Oxide (EO) sterilization and validation testing per ISO 11135:2014 and the 2024 FDA guidance "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff*".

- Simulated transportation and associated package integrity testing in accordance with ASTM D4169-22.

- Shelf-life testing (accelerated aging) per ASTM F1980:21, including package integrity testing (dye penetration test per ASTM F1929-15, seal strength testing per ASTM F88/F88M-21 and visual assessment per ASTM F1886/F1886M-16).

Mechanical Testing

Testing to support structural and mechanical specifications of the subject device was conducted, including pull apart test for the Goldtrace FSE connector and Legplate and three-point bend test for the drive tube and the guide tube. The bend tests demonstrated the material consistency over batches and that the material in the tubes was pliable within the load range.

Comparative Performance Testing

A comparative test was performed between the Goldtrace FSE and the predicate device (K030691). The two devices are equivalent in electrical properties, in their ability to transmit fetal ECG signals and perform equally when used together with Philips Avalon FM30 fetal monitor.

## VIII. CONCLUSION

The performance data described above demonstrate that the Goldtrace FSE is as safe and effective as the predicate device, Fetal Spiral Electrode (K030691) and supports determination of substantial equivalence.