December 3, 2025

Vitalograph Ltd.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K253293
Trade/Device Name: VitaloJAK Clinic (Model 7100)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: November 12, 2025
Received: November 12, 2025

Dear Paul Dryden:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
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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)*
K253293

Device Name
Vitalograph VitaloJAK Clinic (Model 7100)

Indications for Use *(Describe)*
Vitalograph VitaloJAK Clinic Model 7100 is indicated for use to aid in the assessment of cough in adults and pediatric patients aged 8 years and older under supervision presenting with suspected Chronic Cough.

The Vitalograph VitaloJAK ClinicModel 7100 is a non-invasive battery-operated device intended to acquire, record and store ambulatory cough sounds from patients. The device stores the data on internal memory for later playback, review, and analysis on a windows-based PC.

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.

510(k) Summary

Date Prepared:	12-Nov-25
Submitter:	Vitalograph (Ireland) Ltd Gort Road Industrial Estate Ennis Co. Clare V95 HFT4 Ireland +353 65 6864100
Submitter Contact:	James O-Keeffe - CTO
Submission Correspondent:	Paul Dryden, ProMedic, LLC
Proprietary or Trade Name:	Vitalograph VitaloJAK Clinic Model 7100
Common / Usual Name:	Medical Magnetic Tape Recorder
Classification CFR:	21 CFR 870.2800
Product Code:	DSH
Predicate:	Vitalograph VitaloJAK Model 7100
Common / Usual Name:	Medical Magnetic Tape Recorder
Classification CFR:	21 CFR 870.2800
Product Code:	DSH

Device Description:
The Vitalograph VitaloJAK Clinic Model 7100 is a non-invasive battery-operated device intended to acquire, record and store ambulatory cough sounds from patients. The device stores the data on a removable memory card or internal memory for later playback, review, and analysis on a windows-based PC.

The Vitalograph VitaloJAK Clinic Model 7100 is indicated for use in cough recording sessions. It provides the means to sense voice and cough activity from a subject, record this information and store it on an SD memory card. The Vitalograph VitaloJAK Clinic Model 7100 is not life supporting equipment, it does not screen, treat or prevent any condition or disease. The subjects may be of any user population, weight range, health, or condition.

Device Modifications:
The following is the summary of changes in the device under evaluation (Vitalograph VitaloJAK Clinic):

- Name changed to include “Clinic”. Therefore, the device name is “Model 7100 Vitalograph VitaloJAK Clinic”; to differentiate between the device variants and specify it’s use on advice of clinician in the outpatient clinical set-up.
- Maximum test duration of 24 hours is changed to 96 hours.
- Addition of VitaloJAK Studio software application. The VitaloJAK Studio App provides device configuration to perform recording and download the results onto a workstation.
- Microphone and LCD/ display have been removed.
- Redesign of user interface with the four buttons on the front removed and changed to one button on the front of the device for marking events and to mute the device. The second button on the side of the device is to start recording. The on/off button is located inside the battery door. Housing dimensions are modified.
- Memory capacity is increased to 32GB eMMC. The predicate device had a Compact Flash memory card.

Comparison Table

Table of Comparison of Proposed to Predicate Device

Product	**Modified Device** **Vitalograph VitaloJAK Clinic Model 7100**	**Predicate Device** **Vitalograph VitaloJAK Model 7100 (Cough Monitor) (K110525)**	**Substantially equivalent to predicate?**
Model and Device Name	Vitalograph VitaloJAK Clinic Model 7100	Vitalograph VitaloJAK Model 7100	Yes, same name and model number except "Clinic" is added to the name of the changed device as it is used on prescription by clinician in the out-patient department. No impact on product safety and performance. All VitaloJAK variants are used under supervision.
Indications for Use	Vitalograph VitaloJAK Clinic Model 7100 is indicated for use to aid in the assessment of cough in adults and pediatric patients aged 8 years and older under supervision presenting with suspected Chronic Cough. The Vitalograph VitaloJAK Clinic Model 7100 is a non-invasive battery-operated device intended to acquire, record and store ambulatory cough sounds from patients. The device stores the data on internal memory for later playback, review, and analysis on a windows-based PC.	The VitaloJAK is indicated for use in cough recording sessions. It provides the means to sense voice and cough activity from a subject, record this information and store it on an SD memory card. The subject device is not interpretative and does not deliver a diagnosis.	Yes, both are indicated for use for similar indication i.e. cough recording, however the wording is updated in the changed device to differentiate it from Intended use statement and to include specific condition of Chronic cough. Although both the devices are indicated for chronic cough, but it is only now specified in the changed device.
Patient Population	Adults and pediatric patients aged 8 years and older under supervision	Adults and pediatric patients aged 8 years and older under supervision	Similar, though the population was not specified in the predicate, but test data was provided.
Environment of Use	Hospital, clinic or home setting	Hospital, clinic or home setting	Similar

Product	Modified Device Vitalograph VitaloJAK Clinic Model 7100	Predicate Device Vitalograph VitaloJAK Model 7100 (Cough Monitor) (K110525)	Substantially equivalent to predicate?
Principle of Operation	Recording the audio inputs from the Cough Sensor	Recording the audio inputs from the Cough Sensor and Microphone	Yes, the cough sensor is identical. Microphone is removed in the modified device but it does not impact the safety and performance of the device.
Essential Performance Test Limits	Recordings are downloaded to a PC for subsequent analysis via USB or flashcard. A valid sound recording must be present on the cough channel to perform audio analysis. Minimum requirement for a valid audio file for EN60601 testing is no flat line data, indicating no audio was recorded.	Recordings are downloaded to a PC for subsequent analysis by trained Audio Analysts via compact flashcard. A valid sound recording must be present on one of the channels to perform audio analysis. Minimum requirement for a valid audio file for EN60601 testing is no flat line data, indicating no audio was recorded	Yes, Similar, added USB downloaded
Acoustic sensor applied on suprasternal notch	Yes	Yes	Yes, Identical
Non-invasive	Yes	Yes	Yes, Identical
Mute	Yes – Center button on front of the device to mute and to register events during the recording session	No	No muting option in predicate but this feature does not affect safety or effectiveness compared to the predicate
Display	No LCD/ display. LED to monitor various operational states	Monochrome LCD display. Bi-colour status LED to indicate device state	There is a change in the design of the device. LED function is identical however, LCD/Display is removed to minimise operations to make it user friendly. No impact on product safety and performance.
Maximum Test Duration	72 hours on internal memory	24 hours	Yes, similar (now can record four consecutive sessions of 24 hours for up to 72 hours)

Product	Modified Device Vitalograph VitaloJAK Clinic Model 7100	Predicate Device Vitalograph VitaloJAK Model 7100 (Cough Monitor) (K110525)	Substantially equivalent to predicate?
False Positive Cough Rate	None (coughs are manually identified)	None (coughs are manually identified)	Similar
Power Supply	3 x AA Batteries. USB powered during configuration/ download 5V/500mA	4 x AA Alkaline Batteries.	No USB in predicate
Dimensions	84mm x 92mm x 28mm	137 mm x 76 mm x 45.5 mm	Similar device dimensions.
Weight	250g – device only	225 g – device only	Similar
Operating Temperature	5 – 40ºC	0–50ºC	Similar
Operating Humidity	15%–90%RH	10%–95%RH	Similar
Atmospheric pressure	700 – 1060hPa	700 – 1060hPa	Similar
IP rating	IP22 when in pouch - protected against touch by fingers >12.5mm and water spray <15 degrees from vertical.	IP22 when in pouch - protected against touch by fingers >12.5mm and water spray <15 degrees from vertical.	Similar
Service Life	No claim	Same	Similar
Shelf-life of sensor	1 year	1 year	Similar
Memory and Communications	Micro-SD Card: min 8GB, Internal Memory: 32GB, Write speed: 20 MB/sec. USB 2.0/3.0 for data download and device configuration. Custom USB cable is required, supplied with device.	Compact Flash Card. Size: 4GB, Write speed: 20 MB/sec No USB cable	Technology upgrade with increase storage capacity in changed device as compared to predicate. Device is as safe and efficient as predicate
Sampling Rate	8 kHz	8 kHz	Similar

Product	Modified Device Vitalograph VitaloJAK Clinic Model 7100	Predicate Device Vitalograph VitaloJAK Model 7100 (Cough Monitor) (K110525)	Substantially equivalent to predicate?
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (Min), 4GB (Recommended) Disk Space: 1GB or greater. Operating System: Windows 7 or above Monitor: 1280 x 800 pixel Other: Net framework 4.5.1, USB Port	Doesn't required to be connected to a PC, therefore, no minimum requirements	Predicate device does not connect to PC. This does not raise new risks compared to the predicate.
Safety Standards	EN 60601-1:2006+A1:2013+A2:2021	EN ISO 60601:2006 {IEC 60601 - 1:2005}	Similar
Home Use Standard	EN 60601-1-11:2015+A1:2021	EN 60601-1: 2006	Similar
EMC Standards	EN 60601-1-2:2015+A1:2021	EN60601-1-2:2001	Similar
Materials in Patient contact	Laminated hydrocolloid medical grade adhesive Device housing – ABS Plastic Surface contact, Intact skin, Prolonged duration ISO 10993-1 testing	Laminated hydrocolloid medical grade adhesive Device housing – ABS Plastic Surface contact, Intact skin, Limited duration ISO 10993-1 testing	Identical materials. Testing performed is the same for limited or prolonged duration of contact

Discussion of Substantial Equivalence Between Subject and Predicate

Indications for Use –
The indications for use for the subject and predicate device are similar.
Discussion – The change in the length of possible recording time from 24 to 72 hours and inclusion of the population detail which were not presented in the predicate, but testing provided.

Technology and construction –
The technology of the subject and predicate device is identical.
Discussion – There is no difference in the technology and construction between the subject and predicate device with exception of removal of the microphone which is no longer needed.

Environment of Use –
The environment of use is identical.
Discussion – The environments of use are identical to the predicate.

Patient Population –
The patient population of the subject device and predicate is the same.
Discussion – The population is not specified in the predicate device.

Non-clinical Testing
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

- ISO 10993-5 – Cytotoxicity
- ISO 10993-10 – Sensitization
- ISO 10993-10 – Irritation

Though the duration of use of the patient contacting materials has changed from limited to prolonged according to ISO 10993-1, the required tests are the same.

Bench testing
- Post Aging Performance Testing
- Drop Testing
- Transportation Testing
- Testing to the Recommended Operating Conditions
- Durability Testing on Labelling
- Human Factor Validation Testing
- Battery Life Verification
- Mechanical Design Verification
- Real Time Age Testing
- Accelerated Age Testing
- RTC Battery Life Testing
- Design Verification 3rd Party Audio Testing
- Audio Sensor Testing
- Software Testing
- Electronic Design Verification

Substantial Equivalence Conclusion

Through testing, the subject device has demonstrated it is substantially equivalent to the predicate device.