[INSERT Letter Issuance Date]

Ingeniars S.r.l.
Silvia Panicacci
Telemedicine Business Developer
Via Ponte a Piglieri 8
Pisa, IT 56121
Italy

Re: K252440
Trade/Device Name: EasyTeleMed (2.0.2)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: August 1, 2025
Received: August 4, 2025

Dear Silvia Panicacci:

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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252440

Please provide the device trade name(s).

EasyTeleMed (2.0.2)

Please provide your Indications for Use below.

EasyTeleMed mobile applications (Home and Professional) connect with compatible physiological measurement devices intended to be used at home or healthcare-related environments to collect physiological parameters measurements and securely transmit them unaltered to the EasyTeleMed EMR Plus. The physiological parameters that can be acquired are:

- Blood pressure (systolic/diastolic)
- Heart rate (from ECG or auscultation)
- Pulse rate (form finger or arm)
- Body weight
- ECG
- Blood glucose
- Pulse oximetry
- Spirometry
- Body temperature
- Respiratory rate
- Cardiac auscultation
- Pulmonary auscultation

EasyTeleMed serves as Software as a Medical Device and can be used only with specific FDA cleared or approved third-party measurement devices.

EasyTeleMed securely stores the collected information and makes it available for viewing by remotely located clinicians using EasyTeleMed EMR Plus, accessible via a web browser. The clinician can analyze the data, prescribe medications, set up a care plan or contact the patient if needed (via message or video calls). Clinicians can set rules (activities and thresholds) individually for each patient and for any rule breach, notification is sent to the clinician, if desired.

EasyTeleMed does not interpret, make diagnoses nor serve as a substitute for medical care. It is not intended to provide real-time data.

EasyTeleMed is contraindicated for use in high-acuity environments, such as the ICU or operating rooms, and is not intended to use on acutely or critically ill patients or those requiring time-critical or emergency intervention. EasyTeleMed is not intended for use in settings and on patients where the nature of changes in vital parameters is such that they could create an immediate danger to the patient.

EasyTeleMed is intended for patients who are willing and capable of managing its use or can be assisted by a caregiver. Clinical judgement and experience by a clinician are required to check and interpret the information delivered.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252440

510(k) Summary

Prepared on: 2025-08-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ingeniars S.r.l.
Applicant Address	Via Ponte a Piglieri 8 Pisa IT 56121 Italy
Applicant Contact Telephone	(039)0506220526
Applicant Contact	Dr. Silvia Panicacci
Applicant Contact Email	silvia.panicacci@ingeniars.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EasyTeleMed (2.0.2)
Common Name	EasyTeleMed
Classification Name	Transmitters And Receivers, Physiological Signal, Radiofrequency
Regulation Number	870.2910
Product Code(s)	DRG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211822	LifePath Remote Patient Monitoring Platform	DRG
K181248	Comarch e-Care Platform	DRG
K211365	Alio Medical RMS	DRG, FLL, DC
K152139	Vital Connect Platform	DRG, DSI, ML

Device Description Summary

21 CFR 807.92(a)(4)

EasyTeleMed is a flexible and highly configurable telemedicine/telemonitoring platform for data collection, transmission, storage, analysis, visualization and data sharing among medical personnel.
EasyTeleMed is a software-only device, composed by:
• a centralized module, the EMR Plus, an application to be installed on a server machine, exposing a web interface and performing electronic medical record functions;
• two mobile modules:
- Home: a mobile application for patient physiological parameters self-acquisition at home;
- Professional: a mobile application (also available in Point of Care version) for patient physiological parameters acquisition by healthcare operators during visits or in facilities;
The mobile modules are enabled to communicate with a predefined set of COTS measurement sensors to acquire physiological parameters values from patients and forward the data to the EMR Plus module.
The device aims at automatically monitoring at distance physiological parameters and signals, lifestyle information and in general the clinical status of the enrolled patients, and to support the physician decision-making process with clinical evidence.
The system introduces a very high optimization of the out-of-hospital patient management processes, reducing errors due to manual transcription, the delay of information sharing and enabling the healthcare personnel to remotely assign personalized care plans and

monitor at distance patients' health status in a more continuous way with respect to domiciliary or in-hospital visits.
The result is a greater effectiveness and proactivity of the healthcare service. The medical staff, through the device, is able to recognize a worsening situation in the health status of a monitored patient more readily than with periodic visits only, being able to nip worsening situations in the bud and prevent possible hospitalization of the patient.
The device does not replace periodic visits, nor should it be used in place of existing emergency channels/systems.
The high configurability of the system allows the healthcare team to tailor the service on the specific patient's needs and to make adjustment easily during the monitoring period. The health care professional is also enabled, via the EMR, to set thresholds on the physiological parameters values, so that the system can generate notification events if an entered measurement violates one of the set thresholds, thus bringing the patient to the attention of the physician.
The device does not provide for automatic thresholds; thresholds setting is entirely up to the health care staff and each threshold is patient-specific.
Moreover, the device allows for surveys administration, prescriptions, and implements a communication mechanism between patient and physicians via videocalls and messaging.
The device was conceived to refer to a patient population typically with a chronic or postoperative condition with a low likelihood of complications, but this does not preclude the device from being used for other situations as well, should the physician feel that the patient would gain benefits from device employment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EasyTeleMed mobile applications (Home and Professional) connect with compatible physiological measurement devices intended to be used at home or healthcare-related environments to collect physiological parameters measurements and securely transmit them unaltered to the EasyTeleMed EMR Plus. The physiological parameters that can be acquired are:
• Blood pressure (systolic/diastolic)
• Heart rate (from ECG or auscultation)
• Pulse rate (from finger or arm)
• Body weight
• ECG
• Blood glucose
• Pulse oximetry
• Spirometry
• Body temperature
• Respiratory rate
• Cardiac auscultation
• Pulmonary auscultation

EasyTeleMed serves as Software as a Medical Device and can be used only with specific FDA cleared or approved third-party measurement devices.

EasyTeleMed securely stores the collected information and makes it available for viewing by remotely located clinicians using EasyTeleMed EMR Plus, accessible via a web browser. The clinician can analyze the data, prescribe medications, set up a care plan or contact the patient if needed (via message or video calls). Clinicians can set rules (activities and thresholds) individually for each patient and for any rule breach, notification is sent to the clinician, if desired.

EasyTeleMed does not interpret, make diagnoses nor serve as a substitute for medical care. It is not intended to provide real-time data.

EasyTeleMed is contraindicated for use in high-acuity environments, such as the ICU or operating rooms, and is not intended to use on acutely or critically ill patients or those requiring time-critical or emergency intervention. EasyTeleMed is not intended for use in settings and on patients where the nature of changes in vital parameters is such that they could create an immediate danger to the patient.

EasyTeleMed is intended for patients who are willing and capable of managing its use or can be assisted by a caregiver. Clinical judgement and experience by a clinician are required to check and interpret the information delivered.

Indications for Use Comparison

21 CFR 807.92(a)(5)

EasyTeleMed device (subject device) and predicate devices have the same indications for use which is to connect remotely located clinicians with patients located at home/healthcare-related environments to receive care/consultations based on collected vital sign measurements. The subject device can be used in healthcare-related environments (EasyTeleMed Professional) or at home (EasyTeleMed Home) in a manner equivalent to the LifePath Patient App of the primary predicate device, and Comarch SMA application, Alio Bedside Hub and Vital Connect Relay of the secondary predicate devices. They acquire data from third-party measurement devices (in the case of EasyTeleMed, LifePath Remote Patient Monitoring Platform and Comarch e-Care Platform) or from proprietary devices (in the case of Alio Medical RMS and Vital Connect Platform). Collected information is made available for remote clinicians via a web browser (EasyTeleMed, Comarch e-Care Platform, Alio Medical RMS and Vital Connect Platform) or a mobile application (LifePath Remote Patient Monitoring Platform). All devices do not interpret, make diagnoses nor serve as a substitute for medical judgement, are contraindicated for use in

high-acuity environments, such as the ICU and operating rooms, and are not intended to use on acutely or critically ill patients or those requiring time-critical or emergency intervention.

Technological Comparison

21 CFR 807.92(a)(6)

The EasyTeleMed device have same or substantially equivalent technological characteristics with the predicate devices of reference.

• Data collection software: EasyTeleMed device is substantially equivalent to predicate devices. All devices use proprietary software with same intended use (telemedicine system) and have the same technological characteristics, sharing the same Communication method of hub with central server, and Communication with measuring devices.

• Data collection software functionality: same as with the predicate devices, EasyTeleMed collects data from measuring devices and transmits them to a central server.

• Communication method of hub with central server: same as with the predicate devices, EasyTeleMed employs Internet access using local Wi-Fi 802.11 or 3G/4G/LTE cellular network for the communication of the hub with the central server.

• Type of measuring devices which can be interfaced to receiver hub: EasyTeleMed device is substantially equivalent to predicate devices. The subject device uses FDA cleared or approved medical devices designed for home and professional use to measure physiological parameters (e.g., SpO2, pulse rate, heart rate, temperature, blood pressure, blood glucose, body weight, ECG, spirometry, respiratory rate, and auscultation). The primary predicate device (LifePath Remote Patient Monitoring) and the first secondary predicate device (Comarch e-Care) use FDA cleared devices to measure SpO2, pulse rate, skin temperature, systolic and diastolic blood pressure and blood glucose, and SpO2, pulse rate, temperature, blood pressure, blood glucose, weight and spirometry, respectively. The last two secondary predicate devices (Alio Medical RMS and Vital Connect) use proprietary devices to measure heart rate, skin temperature and auscultation data, and ECG, heart rate, heart rate variability, R-R interval, respiratory rate, skin temperature, activity and posture, respectively.
Since the safety and security risk of interfacing a measuring device depends primarily on:
o The communication technology used to communicate with it
o The type of measuring device (physiological parameter acquired)
And since subject device and predicate devices:
o Share intended use
o Share device classification and regulation number
o Use FDA cleared measuring devices
o Use same technological characteristics for communication between measuring devices and hubs
The manufacturer can state that from the safety and security point of view, the substantial equivalence is reached if each measuring device type declared for subject device is declared for at least one predicate device, which is the case.

• Measuring device software: EasyTeleMed device is substantially equivalent to predicate devices. As with the predicate devices, the software of the measuring devices is used unchanged. The only difference is that subject device, primary predicate (LifePath Remote Patient Monitoring) and first secondary predicate (Comarch e-Care) use COTS measuring devices, while second and third secondary predicates (Alio Medical RMS and Vital Connect) uses proprietary measuring devices for the acquisitions.

• Communication with measuring devices: same as with the predicate devices, EasyTeleMed employs short-range radio system using Bluetooth for the communication with measuring devices.

• Method implemented for collecting data from measuring devices: same as with the predicate devices, EasyTeleMed employs Bluetooth v2.0 and higher for collecting data from measuring devices.

• Measuring devices communication frequency: same as with the predicate devices, EasyTeleMed employs Bluetooth operating at 2.4 GHz for the communication with measuring devices.

• Power source: same as with the predicate devices, EasyTeleMed employs a wall power plug (120V AC 50-60) to charge mobile devices and laptops.

• Display: EasyTeleMed device is substantially equivalent to predicate devices. As with the predicate devices, EasyTeleMed employs displays as means of user interaction on third-party medical devices, as well as on both the patient and clinician device modules.

• Communication with patients: EasyTeleMed corresponds to the primary predicate device (LifePath Remote Patient Monitoring) and first secondary predicate device (Comarch e-Care) for this feature. Communication with patients is provided through visual reading and feedback on EasyTeleMed Home (mobile device), chats, email messages, video calls and phone calls from/to caregiver. The second and third secondary predicates (Alio Medical RMS and Vital Connect) do not provide communication with patients.

• Use of thresholds/algorithms for determining how thresholds are set and changed: EasyTeleMed device corresponds to the primary

predicate device (LifePath Remote Patient Monitoring) and the first secondary predicate device (Comarch e-Care) for this feature. Individual patient thresholds are set by the clinician using device interface. The server software compares data received against the pre-set thresholds.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The functionalities of the EasyTeleMed device were verified through a comprehensive software verification plan and validated via the usability engineering process. All functions were tested against requirements and design specifications to ensure each software component performs as intended. The testing was documented in accordance with the FDA Guidance document, "Content of Premarket Submissions for Device Software Functions."
A risk analysis was conducted as per ISO 14971:2019, "Medical devices - Application of Risk Management to Medical Devices" and a Cybersecurity risk analysis was conducted based on ANSI AAMI SW96:2023". All identified hazards were mitigated and residual risk was controlled through risk controls.
A usability engineering process was performed following the standard of ISO 14971:2019, and the 2016 FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices," to identify critical tasks and associated user errors.
The following non-clinical performance data support the determination of substantial equivalence:
1. Verification testing to demonstrate that the software meets established product requirement specifications and that identified risk mitigation measures function as intended.
2. Verification that physiological parameters collected from FDA 510(k) cleared third-party devices were accurately collected, transmitted, stored, and displayed while maintaining data integrity
All non-clinical performance tests on the EasyTeleMed device were successful. The non-clinical performance data, along with the substantial equivalence table, confirm that the EasyTeleMed device is similar to predicate devices and that the risk analysis demonstrates it is as safe and effective as the predicates.

No clinical performance data was collected during the design validation of the EasyTeleMed device, as the Risk Analysis did not identify any features that would introduce safety or performance hazards for users. All known and foreseeable hazards were mitigated through appropriate risk control measures.
The safety and performance of the EasyTeleMed device were determined through software verification testing and a validation performed through usability process.
Claims of substantial equivalence with predicates, are supported with a comparison based mainly on intended use, features, user manuals and technological characteristics.