April 1, 2024

Talis Clinical, LLC
William Murphy
Vice President Regulatory & Quality
650 Mondial Parkway
Streetsboro, Ohio 44241

Re: K233133
Trade/Device Name: Talis EMR with +ACG
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: February 23, 2024
Received: February 26, 2024

Dear William Murphy:

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.

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 Shih 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

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)*

K233133

Device Name

Talis EMR with +ACG

Indications for Use *(Describe)*

+ACG is a Clinical Decision Support device that only matches data to Hospital-defined protocols to generate Alarms and Advisories. +ACG uses data from multiple sources including medical devices and healthcare information systems.

Medical Facilities use their clinical practices, protocols, and policies to define clinically relevant alarms and advisory criteria. Talis then configures Alarms and Advisories within +ACG to be used by the Medical Facility's clinical physicians or appropriate medical staff under the direction of physicians.
+ACG is intended to support the Medical Facility's efforts to improve compliance to their patient care protocols and achievement of their quality initiatives.

It is not intended to replace clinicians' judgement, but rather to assist clinicians in making timely, informed decisions.

+ACG is not intended to be used for secondary monitoring.

+ACG Alarms are not intended to be relied upon in deciding to take immediate clinical action.

+ACG only works with Talis EMR Products.

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.

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510(k) Summary			
I. SUBMITTER			
Date Prepared	March 15, 2024		
Submitter/Owner	Talis Clinical LLC 650 Mondial Parkway Streetsboro, OH 44241 USA Phone: 1-234-284-2400		
Key Contact	William Murphy VP Regulatory & Quality william.murphy@getinge.com		
510(k) Submission Type	This is a traditional 510(k) for multi-function software as a medical device.		
II. DEVICE			
Trade Name	Talis EMR with +ACG		
Common Name	Alarm Notification System		
Classification Name	Panel & Name: Cardiovascular (OHT2) Subpart & Division: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A) 21 CFR 870.2300 Regulatory Class: Class II Product Code: MWI		
III. PREDICATE DEVICE			
Predicate Device	**510(k) No.**	**Company Name** **Device Name**	**Product Code**
	K213335	Capsule Technologies, SAS / Capsule Tech Inc. Capsule Surveillance System	MWI
The Talis EMR with +ACG is substantially equivalent to the legally marketed predicate Capsule Technologies, SAS / Capsule Tech Inc.'s Capsule Surveillance System (K213335).			
IV. DEVICE DESCRIPTION			
Talis EMR with +ACG – description of device per 21 CFR 807.92(a)(4)			
Talis EMR software is an Electronic Medical Record intended to support patient care documentation compliant with patient care record and billing requirements. Talis EMR leverages a non-device MDDS to acquire, transmit, store, and display electronic patient information available from multiple electronic sources including other EMRs and medical devices. Talis EMR provides no clinical recommendations, performs no assessment of patient conditions, and uses no proprietary algorithms. Display or access to patient data is not intended to influence the judgement of the healthcare professional user. Talis EMR software functions are either non-device software functions or software functions for which FDA has determined to exercise enforcement discretion. +ACG software is an alarm notification system which may be configured to notify health care professionals when alarm or advisory conditions are identified based on patient data matching the			

Medical Facility defined alarm or advisory condition criteria. +ACG alarm/advisory notifications are limited to alarm or advisory conditions defined by the Medical Facility.

Medical Facilities use their clinical practices, protocols, and policies to define clinically relevant alarms and advisory criteria. Talis then configures Alarms and Advisories within +ACG to be used by the Medical Facility's clinical physicians or appropriate medical staff under the direction of physicians. +ACG is intended to support the Medical Facility's efforts to improve compliance to their patient care protocols and achievement of their quality initiatives.

+ACG software only works with Talis EMR software.

V. INDICATIONS FOR USE

Intended Use as required per 21 CFR 807.92(a)(5)

+ACG is a Clinical Decision Support device that only matches data to Hospital-defined protocols to generate Alarms and Advisories. +ACG uses data from multiple sources including medical devices and healthcare information systems.

Medical Facilities use their clinical practices, protocols, and policies to define clinically relevant alarms and advisory criteria. Talis then configures Alarms and Advisories within +ACG to be used by the Medical Facility's clinical physicians or appropriate medical staff under the direction of physicians. +ACG is intended to support the Medical Facility's efforts to improve compliance to their patient care protocols and achievement of their quality initiatives.

It is not intended to replace clinicians' judgement, but rather to assist clinicians in making timely, informed decisions.

+ACG is not intended to be used for secondary monitoring.

+ACG Alarms are not intended to be relied upon in deciding to take immediate clinical action.

+ACG only works with Talis EMR Products.

Comparison of Intended Uses for Subject Device and Predicate

Name	**Indications for Use/Intended Use**
Talis EMR with +ACG **Subject Device**	+ACG is a Clinical Decision Support device that only matches data to Hospital-defined protocols to generate Alarms and Advisories. +ACG uses data from multiple sources including medical devices and healthcare information systems. Medical Facilities use their clinical practices, protocols, and policies to define clinically relevant alarms and advisory criteria. Talis then configures Alarms and Advisories within +ACG to be used by the Medical Facility's clinical physicians or appropriate medical staff under the direction of physicians. +ACG is intended to support the Medical Facility's efforts to improve compliance to their patient care protocols and achievement of their quality initiatives. It is not intended to replace clinicians' judgement, but rather to assist clinicians in making timely, informed decisions. +ACG is not intended to be used for secondary monitoring. +ACG Alarms are not intended to be relied upon in deciding to take immediate clinical action. +ACG only works with Talis EMR Products.
K213335	Capsule Surveillance is a clinical decision support device that integrates, analyzes, and displays data from multiple sources including medical devices and healthcare information systems. It

Capsule Technologies, SAS / Capsule Tech Inc Capsule Surveillance System **Predicate Device**	uses standardized rules that are based on customers approved clinical practices, protocols, and policies to create clinically relevant alerts in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended to replace clinicians' judgment, but rather to assist clinicians in making timely, informed, higher quality decisions. Capsule Surveillance may be configured for secondary monitoring and alerting intended to be relied upon in deciding to take immediate clinical action. Capsule Surveillance may also be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Similarities

Item of Comparison	**Description/Rationale**
Target Populations	Both devices are intended to be used by trained clinicians.
Environment of Use	Both devices are intended to be used in medical facility settings.
Matrix and Detailed Views	Both devices allow for matrix or simultaneous multi-patient display or access to detailed views of a single patient's data.
Data Input	Both devices use input from multiple electronic sources including EMRs and medical devices.
Methods for Accessing the Application	Both devices allow access via a workstation or remotely via a web browser
Not intended to be relied upon in deciding to take immediate clinical action.	Both devices may be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.

Differences

Item of Comparison	**Description/Rationale**
Secondary Monitoring	Subject device is not intended for secondary monitoring
Intended to be relied upon in deciding to take immediate action	Subject device is not intended to be relied upon in deciding to take immediate clinical action.
Clinical Surveillance	Subject device does not detect the onset of emergent, potentially actionable conditions and inform the care team.
Patient Monitoring	Subject device is not integrated with a predictive scoring system that calculates a score quickly at the bedside (combining certain vitals and clinician observations) to help in identifying patients at risk of deterioration.
Default Alarms or Advisories	Subject device does not support any clinical alarm or advisory condition unless the medical facility identifies and defines the alarm or advisory condition and messages to the HCP.
Clinical Surveillance	Subject device does not monitor patient conditions

Patient Monitoring	Subject device does not monitor, assess, diagnose, or predict patient conditions. Software is limited to match patient data to Medical Facility defined patient care protocols (guidances)
Intended to be relied upon in deciding to take immediate action	Subject device provides no alarms / advisories not understood by HCP authorized to perform and trained to Medical Facility patient care protocols.

Substantial Equivalence Summary

Both devices provide clinical decision support. Both may be configured to support Medical Facility defined alarms / advisories condition criteria. Both have the ability to send alarm notification signals to HCP as identified by the Medical Facility. Operational and technological characteristics form the basis for the determination of substantial equivalence of the Talis EMR with +ACG software with the legally marketed predicate device (K213335). Talis EMR with +ACG is substantially equivalent to the predicate device.

VI. Performance Data

Non-Clinical Tests – Harmonized Standards

Talis EMR with +ACG has passed all safety tests for demonstrated compliance with the harmonized standards below.

Standard	FDA Recognition #	Title
ANSI AAMI IEC 62304:2006/A1:2016	13-79	Medical device software – Software life cycle processes [Including Amendment 1 (2016)]
ANSI AAMI IEC 62366-1:2015+AMDI:2020 (Consolidated Text)	5-129	Medical devices – Part 1 Application of usability engineering to medical devices, including Amendment 1

Non-Clinical Tests – International Recognized Standard

Talis +ACG Alarm Notification System testing confirmed that the alarm and advisory signals comply with the international standard below.

Standard	Title
ISO 60601-1-8 Edition 2.2 2020-07	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.

Talis EMR with +ACG cybersecurity processes and controls demonstrate compliance with the recognized standard below, as certified by TUV SUD and assessed by 3rd party vulnerability and penetration testing. MedISAO membership also supports identification of newly identified vulnerabilities.

Standard	Title
ISO 27001: 2017	Information technology – Security techniques – Information security management systems – Requirements (ISO/IEC 27001:2013 including Cor 1:2014 and Cor 2:2015) Released 2017-06

Talis Hub hardware which functions as a non-device MDDS was tested to all applicable sections of the standard below, as certified by UL.

Standard	Title
IEC 60601-1 Edition 3.1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Human factors and usability testing has been completed, as well as certification to IEC 62304 for software lifecycle and IEC 62366. No new issues of safety or effectiveness as compared to the predicate are introduced as a result of using this device.

Clinical Studies

Talis EMR with +ACG, like the predicate device, did not require clinical trials.

FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the Talis EMR with +ACG.

Based upon the design, intended use, indications for use, classification, usability, and safety testing the Talis EMR with +ACG is substantially equivalent to the listed predicate device.

VII. CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation, human factors and usability testing demonstrate that Talis EMR with +ACG does not raise new questions of safety and effectiveness when compared to the predicate device, performs as intended, and has performance characteristics that are substantially equivalent to the Capsule Surveillance System predicate device.