DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2016

Braemar Manufacturing, LLC
Kent Sayler
VP Of RA/qa
3890 Murphy Canyon Road, Suite 100
San Diego, California 92123

Re: K153473
Trade/Device Name: Braemar Telemetry Patch System Model BTPS-1000
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: June 21, 2016
Received: June 22, 2016

Dear Kent Sayler:

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 (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. 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.

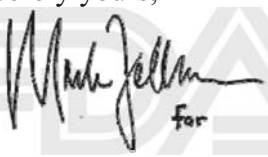
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153473

Device Name
Braemar Telemetry Patch System, Model BTPS-1000

Indications for Use *(Describe)*
The device is designated as Rx only. Its indications for use are as follows:
1. Patients who have a demonstrated need for cardiac Monitoring. These may include but are not limited to patients who require Monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter
9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).
10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.

Contraindications:
1. Patients with potentially life-threatening arrhythmias who require inpatient Monitoring.
2. Patients who the attending physician recommends should be hospitalized for ECG monitoring.
3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.
4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes.
5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes less than or equal to 5% of the peak amplitude.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary Date: 11/25/2015

Submitter Name and Address
Braemar Manufacturing LLC.
3890 Murphy Canyon Road, Suite 100
San Diego, CA 92123

Contact Person:
Kent Sayler
Phone: 619-243-7560
Fax: 858-598-5255

Name of Device

Trade/Proprietary Name:	Braemar Telemetry Patch System, Model BTPS-1000
Common/Usual Name:	Arrhythmia detector and alarm
Classification Name:	CFR §870.1025 Product code DSI 'Arrhythmia Detector and Alarm'
Class:	Class II, Special Controls

Predicate Device
The predicate device selected is as follows:

- **CardioNet Ambulatory ECG Monitor with Arrhythmia Detection Model CN1006** manufactured by CardioNet, Inc. cleared by FDA under 510(k) number K093288 on April 08, 2010.

Note: Effective 1/1/2013, the portion of CardioNet that functioned as a medical device developer / manufacturer became part of Braemar Manufacturing, LLC. Both the predicate device and subject device originated from the company that is now Braemar Manufacturing, LLC.

Device Description

The Braemar Telemetry Patch System BTPS-1000 is an ambulatory ECG monitor with capability to detect cardiac arrhythmias and transmit ECG data to a customer-staffed monitoring center (referred to as "Remote Site").

The subject device is comprised of two (2) main components: 1) a patient-worn Sensor and 2) a Monitor.

The Sensor functions as the data acquisition element in the Braemar BTPS-1000 system. It collects ECG data and transmits it with appropriate Sensor status updates to the Monitor. The Sensor software also manages Leads Off detection and

Pacemaker Pulse detection, monitors battery voltage, motion information, and controls a sounder (beeper) for notifications or warnings. The Sensor software manages battery charging and data retrieval from the Monitor via Bluetooth®. The user interacts with the Sensor software only by connecting the Sensor to the Patch / Electrodes providing a usable battery at which time the Sensor automatically starts. There are four integrated Electrodes built into the Patch, and these adhere to the user. The Electrodes are hardwired to the Sensor within the Patch. There are no Sensor software functions that are controlled or modified by the user.

The Monitor will perform data/arrhythmia detection analysis and transmit the data to the customer Remote Site via cell modem for further post-processing and reporting.

The Monitor software is responsible for managing patient ECG data for the purpose of storage, analysis, and transmission. The Monitor software also performs system integrity checks on itself. The Monitor software provides all visual indications for itself and its associated Sensor. The Monitor also contains software that enables transmission of ECG data via cellular. The user interacts with the software via an On/Off physical button and by touching buttons drawn on the Monitor LCD touch screen. All other physical buttons are disabled and on lock-down by the Monitor, which prevents use of camera and other functions. The user can start/stop the Monitor, declare a symptomatic event, change the screen and speaker intensity levels, and enable/disable the built-in cellular communications. The user can also acknowledge alerts and warnings such as Leads Off or Low Battery, and request help for notices or system messages. The user is not otherwise provided with any means to control or modify software functions

The data is received by trained technicians at the Remote Site who make use of Medical Device Data System (MDDS) software to review the ECG waveforms and determine if they concur with the analysis made by the algorithm in the Monitor.

The Sensor-Monitor network is designed to be operational in a home environment, able to co-exist with other Bluetooth, WiFi, and other protocols operating in the 2.4GHz ISM band. Robustness of Bluetooth networks to interferences from other players in this band is documented in literature (www.bluetooth.com/Pages/Basics.aspx). In addition, attached summary test reports (Attachments T and U) regarding testing specified in IEC60601-1-2 confirm that the device is fully capable of the standard's required safe and effective communication across the cellular (WWAN) and Bluetooth protocols.

The subject device provides continuous ECG recording and automated analysis through operation in MCOT mode (Mobile Cardiac Outpatient Telemetry). Some documentation (including the System Risk Analysis in Attachment G), refers to the subject device as BTPS-1000 MCOT or version 1. The subject device continuously collects ECG data from the patient. The Sensor acquires the ECG data and transmits the data to the Monitor wirelessly. In MCOT mode, the Monitor continuously and automatically analyzes the ECG data using the same proprietary algorithm found in predicate K093288. The data is algorithmically processed and transmitted to customer Remote Site using cellphone.

A proactive approach was used to analyze risks from other features or modes not implemented in the subject device, BTPS-1000 version 1, such as Holter and Event mode, in an effort to "think ahead". Wherever these features are discussed and analyzed in documentation, a comment will be made to clarify said analysis does not apply to BTPS-1000 version 1, which only supports MCOT mode, and the identified risks do not have any impact on safety or effectiveness to BTPS-1000 version 1.

Indications for Use and Contraindications

The subject device is designated as Rx only. Its indications for use are as follows:

1. Patients who have a demonstrated need for cardiac Monitoring. These may include but are not limited to patients who require Monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of breath).

3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring

6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias

7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.

8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter

9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).

10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient Monitoring.

2. Patients who the attending physician recommends should be hospitalized for ECG monitoring.

3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.

4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes.

5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes ≤5% of the peak QRS amplitude.

Comparison of Technological Characteristics with the Predicate Device:

The predicate device has an algorithm subsystem running as part of the software residing on the Monitor as does the subject device. The subsystem analyzes ECG signals received from the Sensor.

The Ambulatory ECG Monitor with Arrhythmia Detection Model CN1006 was selected as the predicate device because the subject device is a modified version of CN1006. The modifications do not alter the intended use or the fundamental scientific technology on which CN1006 is based. The subject device has QT interval measurement capability and ST segment capability, same as the predicate device. The cardiac algorithm on the subject device is the same algorithm as on the predicate device. There are some differences between these two devices:

- The subject device makes use of a Patch/Electrodes-style Sensor that is adhered to the patient's skin and there are no exposed electrode wires as with the predicate device. An internal study included in this submission (reference Attachment BB) showed substantial equivalence regarding ECG analysis between the subject and predicate device. The Sensor's patch form factor allows it to be lighter and smaller.
- There are Sensor and Monitor dimensional differences as provided in Table 5.1.
- The predicate Sensor uses AAA alkaline batteries versus a rechargeable Li-Ion battery used in the subject device. With this, the Sensor has 5 days of battery autonomy.
- The predicate device includes a charging base whereas the subject device utilizes direct charging capability with a charging USB cable.

- The subject device uses Bluetooth® technology for communication between the Monitor and Sensor, whereas the predicate device uses RF at 916 MHz for this communication.
- There are some differences in the operating and storage temperature ranges between the two devices.

Descriptive characteristics and performance testing are used to demonstrate substantial equivalence. The enclosed 510(k) Premarket Notification demonstrates that the subject device is substantially equivalent to the predicate device.

A side-by-side comparison of the Indications and Contraindications between the two devices demonstrates that they are identical. This comparison is included in the Premarket Notification.

Braemar Manufacturing LLC has developed or makes use of standardized tests using the same requirements used in predicate K093288. The predicate 510(k) states that the marketed device complies with the submission.

The Braemar BTPS-1000 device and the predicate device are tested to and comply with all applicable tests and requirements in the relevant standards as stated in the submission. The testing and results are one aspect supportive of Substantial Equivalence to the predicate device.

PERFORMANCE DATA

ECG Study

An in-house clinical study was planned and conducted to provide performance validation demonstrating substantial equivalence between the Braemar predicate device K093288 (referred to internally as C5) using typical ECG electrodes in traditional ECG leads location (lead I and II) and the subject device Braemar Telemetry Patch System (BTPS-1000) using 4 integrated electrodes placed horizontally on the chest (top of the patch 3 fingers down from the clavicle) using ECG waveforms representative of both measures (C5 and BTPS-1000). Beat by Beat comparison between C5 and BTPS-1000 beat detection and classification as well as heart rate measurement performances were generated on twelve volunteers (eight males and four females).

The ECG waveforms from both products showed all the key features in rhythm analysis, including the depolarization of the atria (P wave), depolarization of the ventricles (QRS complex), and the repolarization of the ventricles (T wave). The beat-by-beat statistics provided in TR1811 (Attachment BB) demonstrate that the detection and classification of the 3-lead ECG system (K093288 predicate) and the BTPS-1000 system (subject device) are substantially equivalent. More details are provided in Section 9 of the Premarket Notification.

Biocompatibility

The Patch/Electrode component of the Braemar Telemetry Patch System Model BTPS-1000 resides in contact with the patient's skin for prolonged periods of time. The Patch/Electrodes are procured from Delta Danish Electronics, the owner of the product's design. In accordance with FDA document **"**Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Electrocardiograph Electrodes", Delta has completed a biological evaluation report regarding skin-contacting materials based in ANSI/AAMI/ISO 10993-1 and has determined the Patch/Electrode materials to be biocompatible for their intended use. Braemar has created Biological Evaluation Test Summary Report, located in Attachment P, based on the Delta results to cover all aspects of the testing they performed.

Based on the accumulated use pattern described by Delta, the Patch/Electrode can be classified as a surface device intended to be in contact with intact skin for prolonged duration (> 30 days).

The risk analysis method employed for the BTPS-1000 complies with ISO 14971:2007/(R)2010 (E) – Medical Devices – Application of risk management to medical devices. A fault tree analysis was performed to document the known or foreseeable risks associated with the device, mitigation measures were documented and a residual risk quantity was calculated. This process was repeated until the residual risks were reduced to an acceptable level.

The biocompatibility evaluation for the Braemar BTPS-1000 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within Risk Management Process," as recognized by FDA. This battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

BTPS-1000 Patch Electrode (BTP-1000P)

Four components of the BTPS-1000 Patch Electrode come into direct skin contact with the user, with a nature and duration of contact leading to an accumulated pattern corresponding to prolonged duration. It is evaluated that the components used in the BTPS-1000 Patch Electrode identified to have direct skin contact are not expected to give rise to risks derived from biological or toxicological effects.

These three patient contacting components of the Patch Electrodes are:

1. 3M Siliconized Backing Paper (3M 9834)

2. 3M Non-Woven PET Film (3M 2476P)
3. Hydro Gel Pad AG602
4. PET: Kemafoil HSPL 80W

Documents representing full biocompatibility assessment on all patient contacting components of the Patch/Electrode, including the adhesive on the patch have been generated. See Section 2.5 of the Premarket Notification of this Special 510(k) submission.

In addition to the biocompatibility studies of the four patient contacting components for the Patch Electrodes; the same materials used in the BTPS-1000 Patch Electrode (Delta Danish Electronics design) are used in other legally marketed devices within the same classification. These devices, their assigned 510(k) numbers and materials are:

Subject Device (BTPS-1000 Patch Electrode)	Everyway Lifecare (K083302)	Genmore Reusable Self Adhesive Electrode/Wire Series, Snap Series and Double Sided Series (K062675)	Alelgaard PALS® Nuerostimulation OTC (K132422)
3M Non-Woven PET Film (3M 2476P) 3M Siliconized Backing Paper (3M 9834) Hydro Gel Pad AG602	White spun laced nonwoven tape or polypropylene substrate coated with biocompatible adhesive Conductive Plastic Film Biocompatible Conductive Hydrogel	White spun laced nonwoven tape or white 1/32" thick polypropylene substrate coated with biocompatible adhesive Conductive Plastic Film Biocompatible Conductive Hydrogel	Top Cover Material Stretchable Conductive Fabric Biocompatible Conductive Hydrogel

Delta has conducted real-time aging studies on the Patch/Electrode. As of July 2015, 18 months of real-time shelf life has been documented. The summary test report governing this work is located in Attachment V.

BTPS-1000 Sensor (BTP-1000S)

The BTPS-1000 Sensor, which is activated when attached to the BTPS-1000 Patch Electrode, does not have direct skin contact. Some components of the BTPS-1000 Sensor have limited skin contact to the user and care personnel during cleaning and preparation. The skin contact is considered to be negligible.

BTPS-1000 Monitor (BTP-1000M)

The BTPS-1000 Monitor is a hand-held device that is not connected to the body. There are no adverse effects from the plastic housing. The Monitor is a molded plastic and uses the same polycarbonate material as the mentioned predicate devices. The device does not administer medicinal or chemical agents.

Overall, it is concluded that from a biocompatibility perspective, the BTPS-1000 Sensor, Monitor and Patch Electrode, are safe for the intended use. This therefore is a supportive aspect for the determination of substantial equivalence to the predicate device.

EMC/EMI

The system is designed to function under normal household or office environments. For this reason it is able to coexist with other technologies in common use, such as other Bluetooth devices and WiFi networks. Likelihood of interference by Sensor to other devices is minimal, since the Bluetooth implementation is low power and limited in range. Interference by Monitor to other devices is at a lower level than other common cellular phones, since the cellular modem is not used continuously. The data transmitted by the Monitor only occurs in short bursts with duration of typically less than 20 seconds and usually 1 hour apart. Interference by other devices, at worst case scenario, would cause the Monitor and Sensor to repeat communication attempt. No information is lost since both devices store raw ECG data which is available when prompted by Remote Site. More detail is present in Section 8 of the Premarket Notification.

Software Development & Verification and Validation Testing

Software development efforts were guided by feedback and controls from the risk management process to ensure a safe and effective medical device. Subsequent verification and validation activities were performed to verify correctly implemented design requirements and effectiveness of safety-related controls. All records from verification and validation are traceable to appropriate control.

Mechanical Testing

Mechanical requirements were based upon consideration of all user groups and the environment of each group. For patient use, under the home environment, mechanical properties, such as water resistance, were integrated into the design. The Sensor has been tested to IPX4 water resistance, which is rated to resistance to splashes of water, and the Monitor has been rated to IP67, which can handle immersion of water for a short period of time. See summary reports in Attachments Q and Z.

Other mechanical properties, such as humidity resistance, atmospheric pressure, enclosure properties, such as sharp edges, and transport and storage requirements are addressed by design requirements documents and the risk management process. Test reports by a 3rd party testing facility or internally generated reports are available upon request.

Substantial Equivalence Conclusion

Braemar Telemetry Patch System Model BTPS-1000 is safe, effective, and substantially equivalent to the predicate device as supported by the descriptive information and the performance testing.

Referenced Standards

- AAMI/ANSI EC 57:2012 – Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-47:2012 – Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC60601-1-2:2007, Medical electrical equipment - Part 1-2:General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests (Cardiovascular)
- AAMI / ANSI / ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. (Biocompatibility)
- EC12:2000/(R)2010 – Disposable ECG electrodes
- IEC 60601-1-11:2015 – Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6:2010 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366:2007 – Medical devices – Application of usability engineering to medical devices
- IEC 62304:2006 Medical device software – Software life cycle processes