

## **510(k) Summary** **(As Per 21 CFR 807.92)**

### **SPONSOR**

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Summary Prepared May 19, 2015

Trade Name: **Star 60**

Common/Usual Name: Patient Monitoring System

Classification Name: Physiological Patient Monitor (without arrhythmia detection or alarms)

510(k) Number **K151512**

Product Code: MWI

Device Class: Class II

Regulation Number: 21 CFR 870.2300

### **Predicate Device**

<b><u>Company</u></b>	<b><u>Product</u></b>	<b><u>510(k) #</u></b>
Welch Allyn	Spot Vital Signs LXi	K101680
Philips Medical Systems	SureSigns VS4	K120132
Suntech Medicals	Cycle BP Monitor & Pulse Oximeter, Model 1060	K060820
L&T Medical & Systems	Stellar 300	K103763

## Device Description

STAR 60 is a patient monitor with a wide range of communication options. Capacitive sensing buttons in keyboard is introduced. It fits in clearly to a new age of patient monitoring.

- **ECG+RESPIRATION+TEMPERATURE MODULE:** This module is divided in area and functionality between the main board and the ECG child card. The Temperature section and the DC-DC section of the ER2T lie in the main board.
- **SpO2:** This module is inbuilt inside the monitor on the main board. It is used to measure the partial pressure of oxygen in the human body.
- **NIBP:** This module is inbuilt inside the monitor on to the chassis. It is used to non-invasively measure the systolic, diastolic & mean blood pressure.
- **CO2:** This module is inbuilt inside the monitor on to the chassis. It is used to measure the level of CO2 in the blood (EtCO2 & FiCO2).
- **IBP:** STAR 60 can support IBP modules. For ease of understands we shall name as IBP1 & IBP 2. IBP 1/2 module is inbuilt on the main board. It is used to invasively measure the systolic and diastolic blood pressure.

## Indications for Use

Star 60 multi-parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric or Neonatal patient's vital signs at the bedside or during intra hospital transport along with the appropriate accessories mentioned / supplied with the unit.

Vital signs parameters include ECG (3L/5L), SpO2, Respiration, Temperature, NIBP, IBP and Capnography (CO2). It can also display the numerical values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, FiCO2 readings.

The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

## Summary of Technological Characteristics

Star 60 is designed and developed with reference to our previous 510K cleared product Star55 with same product code as Star60 – MWI.

These 2 products are same in terms of:

- ECG,
- Respiration,
- Temperature,
- IBP,
- NIBP,
- SpO2 and
- CO2
- Display type
- Alarm systems
- Thermal recorder / printer
- Equipment classification, applicable standards

Star60 is compared with MP70 for advanced features that are included in the Star 60 and include:

- Communication with external equipment including analog and system outputs
- Display size and resolution.

Differences between Star 60 and Star 55

The differences between the two devices includes advanced features that include:

- Number of waveform traces displayed
- Waveform display options / selections

The inclusion of the advanced features have been validated and verified to ensure that the new features do not impact performance and the safety and efficacy of the device.

### **Non Clinical Testing**

Electrical and EMC Testing for the Star 60 included the following

IEC 60601-1-2	EMC Test Report
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
IEC 60601-1-8	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
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automatic cycling non-invasive blood pressure monitoring equipment.
IEC 60601-2-34	Medical electrical equipment -- Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment

**Additional Performance Testing:**

ANSI/AAMI EC 13	Cardiac Monitors, Heart rate Meter and Alarms
ANSI/SSMI SP10	Manual, Electronic or Automated Sphygmomanometers
IEC 62304	Medical device software – software life cycle processes (Software/Informatics)
ISO 14971	Application of risk management to medical devices

**Substantial Equivalence**

The Star 60 is substantially equivalent to the predicate device in Indications for Use, Materials and Design. The conclusions drawn from the non-clinical tests demonstrate that the Star 60 is as safe, as effective, and performs as well as or better than the predicate device.

## Indications for Use

510(k) Number (if known)  
K151512

Device Name

STAR 60

Indications for Use (Describe)

Star 60 multi-parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric or Neonatal patient's vital signs at the bedside or during intra hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3L / 5L), SpO2, Respiration, Temperature, NIBP, IBP and Capnography (CO2). It can also display the digital values of HR/PR, SpO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, FiCO2 readings.

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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)

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