February 15, 2021

Zoe Medical, Inc.
Jim Chickering
Regulatory Affairs Manager
460 Boston Street
Topsfield, Massachusetts 01983

Re: K200160
Trade/Device Name: 740 SafeSAT
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN
Dated: February 8, 2021
Received: February 11, 2021

Dear Jim Chickering:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

LT Stephen Browning
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)*
K200160

Device Name

740 SafeSAT

Indications for Use *(Describe)*
The 740 SafeSAT is indicated for use as a bedside, portable device for use by health care professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult and pediatric patients, excluding neonates. The Monitor features technology to facilitate the monitoring of non-invasive blood pressure, pulse rate and functional arterial oxygen saturation (SpO2) in a variety of clinical environments.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

## SUBMITTER

Zoe Medical, Inc.
460 Boston Street
Topsfield, MA  01983 USA

Phone: 978-887-1410
FAX: 978-887-1406

Establishment Registration: 3003294644

Contact Person: Jim Chickering, Regulatory Affairs Manager
Date Prepared: January 3, 2020

## DEVICE

Trade Name:  740 SafeSAT

Common Name:  Patient Physiological Monitor

Classification Product Code:
MWI – Monitor, Physiological, Patient (21 CFR 870.2300)

Secondary Product Codes:
DQA – Oximeter (21 CFR 870.2700)
DXN – NIBP Measurement System (21 CFR 870.1130)

Regulatory Class:  II

Reason for Premarket Notification: New device

## PREDICATE DEVICE

The predicate device is the 740 SELECT patient physiological monitor (K130411).

| Predicate Scope | Predicate Device | 510(k) | Classification |
|---|---|---|---|
| Primary Predicate | 740 SELECT | K130411 | MWI |

The 740 SafeSAT subject device is an alternate construction of the predicate device. In this alternate construction, the Nellcor $SpO_2$ OEM technology is replaced by the "SafeSAT" $SpO_2$ OEM technology, which is manufactured by OSI Optoelectronics (Hawthorne, CA). Furthermore, the neonatal indication is removed from the subject device and the temperature monitoring capability, which is offered optionally in the predicate device, is not offered in the subject device.

No reference devices were used to help support a substantial equivalence determination.

## DEVICE DESCRIPTION

The 740 SafeSAT physiological patient monitor is a portable and rugged non-invasive multi-parameter device used for spot checking, continuous monitoring, and recording of blood pressure, pulse rate, and functional arterial oxygen saturation ($SpO_2$) in a variety of clinical environments.

The 740 SafeSAT monitor employs SafeSAT $SpO_2$ technology which includes the following components from OSI Optoelectronics:

| SafeSAT Component REF | Description |
|---|---|
| 5110 | SafeSAT $SpO_2$ Adult Finger Sensor |
| 5120 | SafeSAT $SpO_2$ Adult Disposable Probe |
| 5130 | SafeSAT $SpO_2$ Adult Soft Tip Probe |
| 5210 | SafeSAT $SpO_2$ Extension Cable |
| 5910 | SafeSAT $SpO_2$ OEM Module |

The 740 SafeSAT monitor is compact and lightweight in design, allowing it to be easily carried or configured for use with a mobile stand, wall mount or on a table top.

A Lithium Ion (Li-Ion) rechargeable battery is provided for automatic switching to back-up power if an unintended loss of AC power should occur as well as allowing the monitor to be used for clinical applications when portable monitoring is required.

The 740 SafeSAT monitor is equipped with a color touch screen which is the primary interface for the user to control and configure the monitor (for patient type, alarms, settings and various clinical workflows). A dedicated message area provides patient alarm and technical messages. Date and time as well as the Monitor ID are displayed. A battery gauge provides battery capacity when the monitor is operating on battery power.

The Monitor supports both point-of-care and variable acuity monitoring. Spot vital signs measurements from multiple patients can be saved individually. The monitor can be used for continuous patient monitoring with full alarm support when increased vigilance is necessary based on patient acuity.

A Standby Mode provides enhanced bedside patient workflow and alarm management by permitting sensor attachment, automatic alarm suspension and a fast transition to active monitoring.

The color-coded Trends Display allows the user to recall all trended physiological patient measurement records. Trends can be recalled for saved snapshots or timed intervals.

The Monitor provides a screen keyboard for entry of patient data (e.g., age, weight, height, gender, date of birth, patient name, and patient identification number).

A serial data output is provided for connectivity to hospital EMR systems. An internal isolated relay switch is provided for attachment to nurse call systems. The Monitor supports an optional, externally connected, thermal strip chart recorder which is directly powered from a serial port.

The MAXNIBP non-invasive blood pressure (NIBP) parameter automatically inflates an occluding cuff and, using the oscillometric measurement technique, determines systolic, diastolic and mean arterial pressure as well as pulse rate. Measurement results along with user prompts and error messages are displayed in the dedicated message area on the display. Automatic, Manual and STAT measurement modes are available to cover a variety of clinical uses.

The pulse oximeter parameter ($SpO_2$) determines arterial hemoglobin oxygen saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. The monitor can display a $SpO_2$ plethysmograph waveform in spot and/or continuous monitoring mode. A signal strength bar provides relative quality of the $SpO_2$ value based on the measurement site where the sensor is placed and the perfusion level of the patient. An audio pulse tone "beep" can be generated each time the $SpO_2$ module detects a pulse.

A pulse rate is displayed and appropriately color-coded to indicate the source parameter ($SpO_2$ or NIBP).

Alarm conditions are displayed as text messages in a dedicated area on the bottom of the display. A recurring series of tones are provided to indicate when an alarm limit has been violated, a condition exists that affects monitoring (e.g., battery low), or a condition exists that affects patient safety. Visual cues (flashing background) are displayed within a parameter cell to indicate when an alarm is currently active for that parameter.

## COMPARISON OF INDICATIONS FOR USE

*The 740 SafeSAT is indicated for use as a bedside, portable device for use by health care professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult and pediatric patients, excluding neonates. The Monitor features technology to facilitate the monitoring of non-invasive blood pressure, pulse rate and functional arterial oxygen saturation ($SpO_2$) in a variety of clinical environments.*

The removal of the neonatal population and the deletion of temperature monitoring from the indications statement in the subject device does not change the intended use of the device relative to the predicate. Temperature monitoring is an optional configuration of the predicate device.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The predicate device and subject device are substantially the same physical device. The subject device uses a different $SpO_2$ OEM technology within the device, with similar patient-applied sensors.

Both the predicate device and subject device employ the well-known method of calculating the patient's $SpO_2$ parameter value, in which the ratio of red to infrared light absorption is measured. This is achieved with 2 LED's (red and infrared) that are illuminated into the patient's tissue in an alternating sequence and a single photosensor that measures the red and infrared light levels in the same alternating sequence.

When sensor motion is detected, the subject device employs a second method for measuring the red and infrared light. This is achieved with a single white LED that is illuminated into the patient's tissue and 2 photosensors that are narrowly sensitive to red and infrared frequencies, which measure the red and infrared light levels simultaneously.

## NON-CLINICAL TESTING

The following tests were performed in accordance with design control regulations to demonstrate substantial equivalence with the predicate device:

- Electrical safety per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-1-2
- Usability per IEC 60601-1-6
- Alarm safety and essential performance per IEC 60601-1-8
- Non-invasive Blood Pressure safety and essential performance per IEC 80601-2-30
- $SpO_2$ safety and essential performance per ISO 80601-2-61
- Software verification per FDA Software Guidance
- Mechanical and environmental safety

The test results demonstrated that all requirements and performance specifications were met.

## CLINICAL TESTING

Clinical studies were performed with all sensors in accordance with the ISO 80601-2-61 standard on pulse oximetry to determine accuracy with respect to blood testing. Additionally, clinical studies were performed in accordance with the ISO 80601-2-61 standard with the Adult Finger Sensor (REF 5110) in the presence of motion artifact. The studies were conducted on healthy male and female adults in the range of 20 to 40 years of age and with a range of skin tone, as outlined in the standard.

No adverse effects or complications were reported during the studies.

The clinical data demonstrates that the device exceeds its performance claims for $SpO_2$ measurement accuracy under motion and non-motion conditions, and supports the determination of substantial equivalence of the subject device.

Given that the $SpO_2$ measurement accuracy claims of the subject device are the same as those of the predicate device, the clinical data supports the substantial equivalence claim to the predicate device.

## CONCLUSIONS

The clinical performance evaluation and non-clinical testing demonstrate that the 740 SafeSAT patient physiological monitor is substantially equivalent to the predicate device with respect to safety and effectiveness.