September 11, 2023

Change Healthcare Israel Ltd.
Alona Golik
Sr. Director, Regulatory Affairs
26 Harokmim St.
Holon, 5885849
Israel

Re: K230881
Trade/Device Name: Change Healthcare Cardiology Hemodynamics™
Regulation Number: 21 CFR 870.2300 and 21 CFR 870.1425
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, DQK
Dated: August 14, 2023
Received: August 14, 2023

Dear Alona Golik:

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,

Robert T. Kazmierski -S

for

LCDR 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)*
K230881/S002

Device Name
Change Healthcare Cardiology Hemodynamics™

Indications for Use *(Describe)*
Change Healthcare Cardiology Hemodynamics™ is intended for complete physiological/hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment. Change Healthcare Cardiology Hemodynamics™ is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

Change Healthcare Cardiology Hemodynamics™ is intended for use in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Use of the system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required.

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

K230881

Change Healthcare Canada Company

1. SUBMITTER

Change Healthcare Israel Ltd.
26 HAROKMIM ST., AZRIELI CENTER,

BUILDING A, HOLON Central, IL 5885849

Contact Person: Alona Golik,

VP Quality Assurance and Regulatory Affairs

Change Healthcare Israel Ltd.

26 HAROKMIM ST., AZRIELI CENTER, BUILDING A

HOLON, Central IL 5885849

Telephone: 972-52-4084942

Email: regulatory@changehealthcare.com

Date Prepared: August 13th, 2023

2. DEVICE

Name of the device:	Change Healthcare Cardiology Hemodynamics™
Common or Usual Name:	Cardiac Monitor
Classification Name:	Monitor, Physiological, Patient, Without Arrhythmia, Detection or Alarms
Classification Regulation	21 C.F.R. § 870.2300 and 21 C.F.R. § 870.1425
Regulatory Class	II
Classification Product code:	MWI
Subsequent Product code:	DQK

3. PREDICATE DEVICE

Name of the device:	Change Healthcare / McKesson Cardiology Hemo ™
510(k) number	K131497
Classification Name:	Monitor, Physiological, Patient, Without Arrhythmia, Detection or Alarms
Classification Regulation	21 C.F.R. § 870.2300
Regulatory Class	II
Classification Product code:	MWI
Subsequent Product code:	DQK

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Change Healthcare Cardiology Hemodynamics™ device is a hemodynamic monitoring system for monitoring vital signs, performing measurements and calculations, documenting procedure and patient data and interfacing to other systems and devices during and after procedures in the area of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

Change Healthcare Cardiology Hemodynamics™ also acquires patient information from other hospital information systems and makes hemodynamic information available to them. It facilitates interfacing with hospital information systems and cardiac image management, archiving and reporting systems.

Change Healthcare Cardiology Hemodynamics™ incorporates the Argus PB-3000 vital signs monitoring device (K221056), manufactured by Schiller AG, which provides patient monitoring via:

- ECG leads
- Invasive Blood Pressure (connected to non-Change Healthcare transducers)
- SpO2 finger clip
- Non-invasive blood pressure (NIBP) cuff
- Temperature probe
- Thermal Dilution Cardiac output temperature probe (connected to non-Change Healthcare Cardiac Output catheter)

- CO2 (connected to non-Change Healthcare cannulas or intubation tubes)

Argus PB-3000 monitoring device is provided with compatible accessories (cables, sensors, cuffs, probes, etc). Appendix L of the Change Healthcare Cardiology Hemodynamics User Guide includes a List of qualified PB-3000 accessories.
Change Healthcare Cardiology Hemodynamics™ is composed of:

- A control and documentation unit (Information System) that is used for administration, performing measurements, recording full disclosure, taking samples and entering procedure notes and overall data input and management of the patient and procedure data.
- A Clinical System that incorporates the RT Monitor and the Front-end (which incorporates the Schiller Argus PB-3000 device). The clinical system is responsible for acquiring, analyzing, and displaying patient vitals and other pertinent clinical data. The data is displayed on monitors.

Change Healthcare Cardiology Hemodynamics™ uses an interface that displays patient data, procedure data, waveforms, and numeric values. The performing physician views the monitor, and conveys instructions and procedure notes to the technician, who operates the application using a touch screen, keyboard and mouse, for maximum convenience.

The control and documentation unit (Information System) can function independently from the Clinical unit and therefore can be setup without the clinical unit for instances where only patient/procedure documentation is required.

In addition, the Change Healthcare Cardiology Hemodynamics™ system can receive and/or export data from 3rd party devices and systems. One such utilization is the ability to import monitored parameter data from 3rd party bedside monitors for documentation purposes as part of the patient's log (part of the Holding Area Charting configuration). This import is performed via the utilization of FDA cleared Capsule's SmartLinx software (K200856) that is intended for clinical information management through networks with independent devices.

Physicians can instruct the technician to configure the appearance, content and layout of the display on the monitors that display the patient's vitals and other pertinent clinical data (real-time monitors) and to perform real-time functions and measurements using the tools that exist in the control and documentation unit. This pane can be shown or hidden at any time by clicking Procedure Control in the display control bar. Each pane in the real-time controls area can be expanded to show more content and contracted to save space when that content is not needed. Changes should be made only upon request or instruction of the physician.

The clinical system resides on a dedicated computer to ensure that it is not vulnerable to failure of the network or the backend computer on which the application resides. In case of application failure, the system knows how to restart itself and restore a stable OS environment on the computer. Watchdogs are in place to prevent failure.

5. INDICATIONS FOR USE/ INTENDED USE

Change Healthcare Cardiology Hemodynamics™ is intended for complete physiological/hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment. Change Healthcare Cardiology Hemodynamics™ is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

Change Healthcare Cardiology Hemodynamics™ is intended for use in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Use of the system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the features and functionalities in the Change Healthcare Cardiology Hemodynamics™ compared to the predicate are as follows in the table below:

Feature	**Comparison Between Subject Device K230881 and Predicate Device K131497**
Indications for Use	Identical. The indications are unchanged, which includes the indicated environment for use and associated procedures.
Vital Signs Acquisition Unit (Hardware)	Substantially Equivalent. The front-end unit for patient parameters acquisition (vital data signs) hardware has been changed from the Schiller AG's Argus PB-1000 (K012226) to the PB-3000 (K221056). The verification testing in the subject 510(k) shows that the new PB-3000 is substantially equivalent to the predicate device.
Monitored Parameters, Waveforms and Patient Connections	Identical. The subject device provides the same display of waveforms and clinical parameter monitoring (ECG, SpO2, IBP, NIBP, Temperature, TDCO, CO2 (capnogram), Resp, FFR), via the same connections to the patient (ECG, IBP, SpO2, NIBP, TDCO, Temp, CO2), as the predicate device.

Calculations and Clinical Formulas	Substantially Equivalent. The clinical formulas provided by the predicate and subject device are identical and the calculations are substantially equivalent, as they rely on the same measurements. The subject Hemodynamics device incorporates an added functionality of Peak Instantaneous Gradient measurement, in addition to the existing Peak-to-Peak and Mean Gradient measurements. The the verification of this calculation shows substantial equivalence to the predicate device.
Operating System and database engines	Substantially Equivalent. Newer versions were implemented in the Change Healthcare Cardiology Hemodynamics™ device that add robustness and reliability to the platforms.
Communication with External Systems	Identical. The Image, Document and Data Export file formats, Communication protocol, Network infrastructure remain identical between the subject and predicate devices.
Alarms	Substantially Equivalent. Both the subject and predicate devices have alarm systems (visual/audio). The subject Hemodynamics device has technical alarms, in addition to physiological alarms that are part of both the predicate and subject devices. The updates for the Alarm functionality (addition of Technical Alarms) are done in compliance with the current IEC 60601-1-8 standard, and therefore demonstrates substantial equivalence to the predicate. .
Other Software Updates	Substantially Equivalent. Software updates improve robustness and security of the device, and the software verification demonstrates substantial equivalence to the predicate device. .

7. NON-CLINICAL PERFORMANCE DATA

7.1. Electrical Safety, Electromagnetic Compatibility (EMC), and additional Standards Testing

The system has been tested and proved to comply with the FDA recognized consensus standards listed below:

Title of the Consensus Standard	FDA Recognition #
AAMI ANSI ES60601-1:2005/(R)2012 + A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	19-4
IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment - Part 1-2:	19-36

General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances - Requirements and Tests	
IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability	5-89
IEC 60601-1-8:2006 Amd 1:2012, 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	5-76
IEC 60601-2-27:2011, Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment	3-126
IEC 80601-2-30:2018, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (NIBP automated)	3-123
IEC 60601-2-34:2011, Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	3-115
ISO 80601-2-55:2018, Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors	1-140
ISO 80601-2-56:2017, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (Temperature)	6-421
ISO 80601-2-61:2017, Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (SpO2)	1-139

7.2. Software Verification and Validation Testing

Title of the Consensus Standard	**FDA Recognition #**
IEC 62304:2015, medical device software - software life cycle processes	13-79

Software Verification and Validation testing was performed at the unit, integration and system levels for the Change Healthcare Cardiology Hemodynamics™ software to ensure it meets all specifications. Usability testing was performed where applicable. In all instances, Change Healthcare Cardiology Hemodynamics™ functioned as intended and the observed results demonstrate substantial equivalence with the predicate device.

7.3. Clinical Testing

No clinical testing was necessary to support substantial equivalence.

8. CONCLUSION

Change Healthcare Cardiology Hemodynamics™, the subject of this submission, is substantially equivalent to the previously cleared Change Healthcare/McKesson Cardiology Hemo (K131497). Change Healthcare Cardiology Hemodynamics™ has the same intended uses and indications, technological characteristics, and principles of operation as the predicate device and as demonstrated by the performance data in the submission.