October 22, 2018

Comarch Healthcare SA
% Jigar Shah
Consultant
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K181248
Trade/Device Name: Comarch e-Care Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: September 18, 2018
Received: September 19, 2018

Dear Jigar Shah:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181248

Device Name
Comarch e-Care Platform

Indications for Use *(Describe)*
The Comarch e-Care Platform is intended to connect with physiological measurement devices (weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers, spirometers, glucometers) intended to use at home and send the measurement results to central server. Comarch e-Care Platform serves as Software as a Medical Device and can be used only with FDA cleared measurement devices.

Comarch e-Care Platform displays the collected measurements on the Web application and securely stores them in a database server, where the caregiver can view the results, analyze them, leave comments and contact patient if necessary. Caregivers are able to set thresholds individually for each patient. Measurement results sent to e-Care Platform from connected devices are analyzed and if result is beyond the threshold, caregiver gets the notification.

The Comarch e-Care Platform is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The Comarch e-Care Platform is contraindicated for patients requiring direct - medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

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.

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"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

The assigned 510(k) number is: K181248

1. **Submitter's Identification:**

COMARCH HEALTHCARE SA
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Phone +48 12 646 10 00
Fax +48 12 646 11 00

Date Summary Prepared: September 18, 2018

Contact: Irmina Serafin,
COMARCH HEALTHCARE SA

2. **Name of the Device:** Comarch e-Care Platform

Regulation Number: 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: II
Product Code: DRG
Common or Usual Name: Remote Patient Monitoring System

3. **Information for the 510(k) Cleared Device (Predicate Device):**

Primary Predicate:
Intel® Health Guide Express, K103276

Reference Predicates:
HealthInterlink Beacon, K133252
MedApps 2.0 Remote Patient Monitoring System, K124000

4. **Device Description:**

Comarch e-Care Platform is a software intended for use in remote patient monitoring outside of traditional healthcare settings (e.g. at home). Components of Comarch e-Care Platform are: Comarch SMA application, Comarch e-Care application, application server, database server.

Comarch SMA is a software application intended to use by patients. It is designed to collect, display and transmit vital sign measurements captured from commercially available home monitoring devices.
The following vital signs are collected: temperature, glucose, noninvasive blood pressure, pulse oximetry, weight and spirometry.

The list of the FDA cleared devices that the Comarch SMA receives readings from:

Device type	**Manufacturer**	**Model**	**510(K) Number**
Ear thermometer	ForaCare Suisse AG	FORA IR21b	K090395
Pulse oximeter	Nonin Medical, Inc.	WristOx2	K052829
Pulse oximeter	Nonin Medical, Inc.	Onyx II	K051107
Scale	A&D Medical	UC-351PBT-Ci	Exempt
Scale	A&D Medical	UC-355PBT-Ci	Exempt
Blood pressure monitor	A&D Company Limited	UA-767PBT-Ci	K043217
Spirometer	Vitalograph	Asma-1	K073155
Spirometer	Vitalograph	Lung Monitor	K073155
Spirometer	Vitalograph	COPD	K073155
Spirometer	MIR	Spirobank II	K061712
Glucometer	TaiDoc Technology Corp.	TD-4277	K100322

5. **Indications for Use:**

The Comarch e-Care Platform is intended to connect with physiological measurement devices (weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers, spirometers, glucometers) intended to use at home and send the measurement results to central server. Comarch e-Care Platform serves as Software as a Medical Device and can be used only with FDA cleared measurement devices.

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6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Feature	Primary Predicate Intel ® Health Guide Express (K103276)	Reference Predicate HealthInterlink Beacon (K133252)	Reference Predicate MedApps 2.0 Remote Patient Monitoring system (K124000)	Subject Device Comarch e-Care Platform (Pending)
Indication for Use	The Intel® Health Guide Express is intended to collect vital signs measurements from physiological measurement devices intended for use at home. Patients can review the stored vital signs measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.	The HealthInterlink Beacon device is for use by patients to collect and transmit general health information, physiological measurements such as blood pressure, temperature, weight, glucose and SpO2 using commercially available FDA cleared wireless medical devices designed for home use, and other data between themselves and a caregiver.	The MedApps 2.0 - Remote Patient Monitoring System is intended to connect to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters then receive and store data collected from measurements then transmit. Healthcare professionals can review the transmitted information.	Comarch e-Care Platform is intended to connect with physiological measurement devices (glucose meters weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers and spirometers) intended to use at home and send the measurement results to central server. Comarch e-Care Platform displays the collected measurements on the Web application and securely stores them in a database server, where the caregiver can view the results, analyze them, leave comments and contact patient if necessary.
Intended use	Telemedicine system	Same	Same	Same
Intended users	Home users and healthcare providers.	Same	Same	Same
Patient population	Medical device is intended for adult users.	Same	Same	Same
Site of use	Healthcare related environment or home	Same	Same	Same
OTC and/or Rx	Rx	OTC and Rx	OTC	Rx

Feature	Primary Predicate Intel ® Health Guide Express (K103276)	Reference Predicate HealthInterlink Beacon (K133252)	Reference Predicate MedApps 2.0 Remote Patient Monitoring system (K124000)	Subject Device Comarch e-Care Platform (Pending)
Data collection software	• Intel® Health Care Management Suite software application • Intel® Health Guide Express software application	• HealthInterlink Beacon Software application	• MedApps proprietary software application	• Comarch e-Care software application • Comarch SMA software application
Data collection software functionality	Transmit data from measuring devices and store data in a central database.	Same	Same	Same
Communication method of hub with central server	Connection via Internet using interface provided by „commercial off the shelf" PC	Via public telecommunications network.	Via embedded cellular technology.	Any Internet access method with Ethernet or Wi-Fi 802.11 b/g/n interface or 3G/4G network.
Types of measuring devices which can be interfaced to receiver hub	Medical Devices designed for home use: glucose meters, weight scales, blood pressure meters, pulse oximeters, peak flow meters	Medical Devices designed for home use: glucose meters, weight scales, pulse oximeters, thermometers, spirometers	Medical Devices designed for home use: glucose meters, weight scales, blood pressure meters, pulse oximeters, peak flow meters	Medical Devices designed for home use: glucose meters weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers, spirometers
Implementation method of collecting data from measuring devices	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth
Measuring device software	Measuring device software unchanged	Same	Same	Same
Connectivity	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth
Communication method of hub with measuring devices.	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth	Short range radio system using Bluetooth and tethered cables	Short range radio system using Bluetooth

Feature	Primary Predicate Intel ® Health Guide Express (K103276)	Reference Predicate HealthInterlink Beacon (K133252)	Reference Predicate MedApps 2.0 Remote Patient Monitoring system (K124000)	Subject Device Comarch e-Care Platform (Pending)
Implementation method of collecting data from measuring devices.	Wireless (Bluetooth) V2.0 & Wired (Tethered)	Bluetooth v2.0 and Bluetooth v4.0	Wireless(Bluetooth) V2.0 & Wired (Tethered)	Bluetooth v2.0 and Bluetooth v4.0
Measuring devices communication frequency	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz
Power source	Wall power plug (120 VAC/50-60)	Same	Same	Same
Display	On devices and hub, and monitors connected to central server	Same	Same	Same
Communications with patients	On screen display.	On screen display. Text/Interactive Voice Response	Audio/visual reading feedback on screen and by speaker and Interactive Voice Response (IVR) System for patient contact	Visual reading and feedback on hub's screen. Phone call and email messages from caregiver
Use of thresholds/algorythms for determining how thresholds are set and changed	Thresholds are set by Healthcare professionals in server software	N.D.	Thresholds are set by Healthcare professionals in server software	Thresholds are set by Healthcare professionals in server software and sent to the hub. Hub performs the analysis and sends it back with results to server software

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The submitted Comarch e-Care Platform has undergone design control verification and validation testing. Comarch e-Care Platform validation testing includes testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP. Comarch e-Care Platform verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis and Verification plans. Comarch e-Care Platform Verification Plan execution ensures the system works with each type of user accessory medical device as part of the Comarch e-Care Platform system. The output of these design control verification analysis documents for the Comarch e-Care Platform system shall meet its requirements and design specifications as intended.

8. Discussion of Clinical Tests Performed:

No new hazards to safety or effectiveness are presented by Comarch e-Care Platform, therefore, no clinical tests were conducted.

9. Conclusions:

Comarch Healthcare SA considers Comarch e-Care Platform to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.