



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 12, 2016

HealthChek Network, LLC
% John Ziobro
Principal Consultant
SpectraMedEx, LLC
117 W. South Street
Oconomowoc, Wisconsin 53066

Re: K152107

Trade/Device Name: Healthchek Network Health Station, Model HCK - 2000
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, FRW
Dated: March 3, 2016
Received: March 9, 2016

Dear John Ziobro:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored FDA logo watermark.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152107

Device Name
HealthChek Network Health Station, Model HCK - 2000

Indications for Use (Describe)

The HCK - 2000 (health station) is an automated system intended to be used by the general adult public, in public environments, so that the user can measure his/her own health parameters such as blood pressure, heart rate, Body Mass Index (BMI) and body weight. It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional. For personal reference purposes, the user can also choose to print or store their data on the HealthChek network's database.

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.

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HealthChek Network
Health Station, Model HCK – 2000
Traditional 510(k) Summary - REVISED

VOLUME 2

SECTION 3

Traditional 510(k) Summary

1. Summary Date 3/3/2016
2. Applicant Name: HealthChek Network, LLC
135 West Sallier St.
Lake Charles, LA 70601
Ph 608-320-636
Establishment Registration Number: Pending
3. Submission Correspondent: On behalf of HealthChek Networks, LLC, the following consultant is assigned the responsibility of submission correspondence:
John F. Ziobro, Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, WI 53018
Ph: 262.719.8922
4. Trade Name: HealthChek Network Health Station, Model HCK – 2000
5. Common Name: Health Kiosk
6. Description: Noninvasive blood pressure measurement system (Per FDA classification)

The HealthChek Network Health Station, Model HCK – 2000 is a kiosk designed for use by the general adult public in public locations to measure the user's health parameters such as blood pressure, heart rate, Body Mass Index (BMI) and body weight. The HealthChek Network Health Station kiosk is not a diagnostic device. It does not introduce any novel modes of operational theory.
7. Manufacturing Site: GMI Solutions
10202 North Enterprise Drive
Mequon, WI 53092 USA
(262) 242-8800
Establishment Registration Number: 2134848
8. Suggested Classification Regulation, Class & Product Code & Panel (NIBP unit):
21 CFR 870.1130
Class II
Product Code: DXN
Panel: Cardiovascular
9. Additional Suggested Classification Regulation, Class & Product Code & Panel (Patient scale):
21 CFR 880.2720
Class I
Product Code: FRW
Panel: General Hospital & Personal Use
10. Reason for Traditional 510(k): New submission
11. Predicate Device(s): 510(k) Number: K123539
Manufacture: StayHealthy
Trade Name: HealthCENTER Biometric Screening Kiosk
Product Code: DXN (Noninvasive blood pressure measurement system)
HIT (Color vision tester)
MNW (Impedance plethysmograph)
Classification: DXN: 21 CFR 870.1130



HealthChek Network
Health Station, Model HCK – 2000
Traditional 510(k) Summary - REVISED

VOLUME 2

SECTION 3

HIT: 21 CFR 886.1170 (510(k) Exempt)
 MNW: 21 CFR 870.2770 (510(k) Exempt)

12. Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:

Quality System Standards.

- CFR 21CFR820: Part 820 – Quality System Regulations
- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes

Safety Standards / Testing Compliance:

- IEC 60601-1:2005 3rd edition General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 3rd edition Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (with immunity testing to IEC 60601-1-2:2014 4th edition)
- IEC 80601-2-30:2009 Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

Design Standards

- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- 47CFR Part 15 Federal Communications Commission (FCC)
- 2002/95/EC Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)
- HIPAA Compliant

13. Indication for Use

The HCK - 2000 (health station) is an automated system intended to be used by the general adult public, in public environments, so that the user can measure his/her own health parameters such as blood pressure, heart rate, Body Mass Index (BMI) and body weight. It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional. For personal reference purposes, the user can also choose to print or store their data on the HealthChek network's database.

14. Technological Characteristics

The hardware and software is very similar to other products on the market and does not differ significantly in any respect. This system is combines the hardware and software platforms of the predicates and as such has identical technological characteristics.

15. Testing

Bench Testing was conducted on a unit with all design options (card reader, printer, etc.) per the requirements of IEC 60601-1 as well as the requirements for blood pressure units (per IEC 60101-2-30). Testing shows that the device is in compliance with the cited standards. Because of the long-established use of health monitoring kiosks, no clinical trial was performed.

16. Comparison to Predicates

The main difference between the proposed device and its predicate pertains to the physiological parameters that are measured. Both devices measure blood pressure and heart rate (using the same module supplied by Suntech), and both measure weight. However, the proposed device measures Body Mass Index (BMI) using the measured weight and a height value that the user manually enters. The predicate device instead presents three similar but distinct values, namely the Percent lean body mass, the Percent body fat and the Percent total body water. In addition, the predicate device tests for color blinded and has an option to present hydration. Of all of these parameters, Blood Pressure is regulated as a Class II device subject to 510(k) market clearance and the differences the alternative measured parameters in do not affect the relative safety and/or effectiveness. For additional information see Table 1.



**HealthChek Network
Health Station, Model HCK – 2000
Traditional 510(k) Summary - REVISED**

VOLUME 2

SECTION 3

17. Conclusions

HealthChek believes proposed HealthChek Network Model HCK-2000 and its predicate, the StayHealthyHealthCENTER Biometric Screening Kiosk System, are substantially equivalent in their intended use, intended users, intended use environment and indications for use. Furthermore, both systems have the same/equivalent technological characteristics, physical characteristics and safety standards. The main difference that exists between the devices, relating to the measured physiological parameters do not affect the relative safety and/or effectiveness or the intended use/indication for use of the device

Table 1: Substantial Equivalence Comparison

Feature	HealthChek Network Model HCK - 2000 (Health Station System Under Review)	StayHealthy HealthCENTER Biometric Screening Kiosk (Cleared under K123539)	Substantial Equivalence Comments
COMPARISON OF USES/INDICATIONS			
Intended Use / Indication for Use	The HCK - 2000 (health station) is an automated system intended to be used by the general adult public, in public environments, so that the user can measure his/her own health parameters such as blood pressure, heart rate, Body Mass Index (BMI) and body weight. It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional. For personal reference purposes, the user can also choose to print or store their data on the HealthChek network's database.	The Stayhealthy SH-650 is intended to be used by the general public so that the user can measure his/her own blood pressure, heart rate, percent lean body mass, percent body fat, percent total body water, body weight, and if the user may have color blindness. It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional. The user can also choose to print the data or send the data to a personal physician or a healthcare professional.	Both devices are for use by the general public to monitor general health parameters. Although the devices measure different parameters, neither device nor any of the measured parameters are used for diagnostic purposes. In addition, the proposed device does not allow the user to transmit their data to a healthcare professional. Instead the data is automatically stored on the HealthChek's database and is made available to the user for their reference. This is a marketing feature and does not affect the safety of the user. Therefore, Substantially Equivalent
Intended User	General Public	General Public	Both devices have identical intended users. Therefore, Substantially Equivalent
Intended Use Environment	General Public Environments	From Website: Business, Government, Home, Research, Health Clubs, Hospitality, Housing Care Facilities, Schools, Retail	Both devices have similar intended use environments. Therefore, Substantially Equivalent
Target Patient Population	General Public	General Public	Both devices have identical targeted patient populations. Therefore, Substantially Equivalent
Contraindicati ons	None	None Stated	Both devices have no, or no known contraindications. Therefore, Substantially Equivalent.
Warnings	As it appears on the mandrel: *WARNING* This cuff is not designed for very large arms. Your arm should fit comfortably with your palm on the arm rest. DO NOT FORCE YOUR ARM INTO THE CUFF, AS DISCOMFORT OR INJURY MAY OCCUR. TO RELEASE PRESS THE RED STOP BUTTON As it appears in the manual: Warning, this machine may bruise you, and you may faint while using it. Do not use it if you are sensitive to pressure on your arm, or have experienced fainting or dizziness. If the pressure on your arm bothers you, or if unexpected readings are obtained, immediately touch the 'STOP' button to deflate the cuff. WARNING, if you receive unexpected blood pressure readings, please contact the kiosk	Warning This cuff is not designed for very large arms. DO NOT FORCE YOUR ARM INTO THE CUFF, TEMPORARY DISCOMFORT OR INJURY MAY OCCUR. Your arm should fit comfortably, with your elbow and forearm on the arm rest. TO RELEASE, PRESS THE STOP BUTTON.	Because both devices use the same blood pressure cuff mandrel, they have identical warnings on it. The predicate device manual does not contain any cautions, warnings or other use restrictions while the proposed device does, including a description of the circumferences that the NIBP module and cuff were designed to operate under. These additional warnings can help aid patient safety. The manual of the proposed device includes a section on Warnings, Safety precautions and Restriction on use. The predicate device does not. The inclusion of a restriction for use on neonatal, pregnant and pre-



HealthChek Network Health Station, Model HCK – 2000 Traditional 510(k) Summary - REVISED	VOLUME 2
SECTION 3	

Feature	HealthChek Network Model HCK - 2000 (Health Station System Under Review)	StayHealthy HealthCENTER Biometric Screening Kiosk (Cleared under K123539)	Substantial Equivalence Comments
	<p>administrator. If you are concerned about your blood pressure, please discuss with a medical professional</p> <p>Warnings, Safety Precautions and Restrictions on Use</p> <p>WARNING, the blood pressure measurement is not intended for use on neonatal, pregnant, or pre-eclamptic patients.</p> <p>When taking blood pressure. The recommended position is comfortably seated, relaxed, legs uncrossed, feet flat on the floor, middle of cuff at level of heart right atrium. It is recommended that 5 minutes should elapse before the first reading is taken. Any reading can be affected by the measurement site, the position of the patient, exercise, the patient’s physiologic condition, common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling or shivering. Readings can also be affected by extremes in temperature, humidity, and altitude. If unexpected readings are obtained, contact your physician immediately</p> <p>As it appears in the manual and onscreen:</p> <p>WARNING, the circumference of user’s arm should be within 24-38cm (9.5 to 15 inches) for best results</p>		<p>eclamptic patients is in compliance with IEC 80601-2-30 clause 201.7.9.2.1 2. These additional restrictions on use can help aid patient safety</p> <p>Therefore, Substantially Equivalent</p>
Use limitations	It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional.	It is not a diagnostic device and only furnishes data so that users can consult their personal physicians or other healthcare professional	Both devices have identical use limitations. Therefore, Substantially Equivalent
FDA Product Code	DXN (Noninvasive blood pressure measurement system) FRW (Weight)	<ul style="list-style-type: none"> • DXN (Noninvasive blood pressure measurement system) • HIT (Color vision tester) • MNW (Impedance plethysmograph) 	Both devices use the same FDA product code for the regulated aspect of blood pressure measuring. The predicate device did not list product code FRW even though it measures weight; their omission does not have an impact on the substantial equivalence determination. The predicate device includes alternative features and therefore cites additional FDA product codes. However, the additional features do not substantially deviate from either device’s intended use as a general health and well-being monitoring system and do not raise any concerns for safety and effectiveness. Therefore, Substantially Equivalent
COMPARISON OF MEASURED PARAMETERS / SYSTEM CONFIGURATIONS			
Measured Physiological Parameters – From 510(k)	<ul style="list-style-type: none"> • Blood pressure, BP (uses the SunTech Advantage Model 2 module, containing the ct3.39.0 firmware and equipped with the SunTech Kiosk Cuff (part # 98-0231-00-AD. REV B); capable of recording blood pressures from +40 to +260 mm Hg Systolic and +20 to +200 mmHg Diastolic • Heart rate (calculated via the BP module) capable of recording rates from 30 to 220 beats per minute • BMI (Body Mass Index) (via a calculated value using the NIH’s algorithms using a height value 	<ul style="list-style-type: none"> • Blood pressure, BP (uses the SunTech Advantage Model 2 module, containing the ct3.39.0 firmware and equipped with the SunTech Kiosk Cuff (part # 98-0231-00-AD. REV B); capable of recording blood pressures from +40 to +260 mm Hg Systolic and +20 to +200 mm Hg Diastolic • Heart rate (calculated via the BP module) capable of recording rates from 30 to 220 beats per minute 	Both devices measure blood pressure and heart rate using the same third party blood pressure module. Both devices measure weight using a load cell. The proposed device measure BMI, while the predicate device measures percent lean & fat mass. The predicate device also tests for color blindness which the proposed device does not do. However, these features do not substantially change the overall



**HealthChek Network
Health Station, Model HCK – 2000
Traditional 510(k) Summary - REVISED**

VOLUME 2

SECTION 3

Feature	HealthChek Network Model HCK - 2000 (Health Station System Under Review)	StayHealthy HealthCENTER Biometric Screening Kiosk (Cleared under K123539)	Substantial Equivalence Comments
	<p>entered by the user) No indicated range as this is a function of height and weight</p> <ul style="list-style-type: none"> Body weight, (tested at 440 lbs / 200 kg) (as measured via a load cell imbedded in an ADA compliant seat) 	<ul style="list-style-type: none"> Percent lean body mass (via bioimpedance) Percent body fat (via bioimpedance) Percent total body water (via bioimpedance) Body weight, (up to 500 pounds / 227 kg) (via a load cell imbedded in an ADA compliant seat) If the user may have color blindness 	<p>design intention of the device and the differences in parameters can be considered to be “marketing” features.</p>
Additional / Alternative Measured Physiological Parameters – From Website	None	<ul style="list-style-type: none"> Hydration-The Stayhealthy Hydration Index (SHI), which calculates on an individual basis, your specific hydration status based on broad population averages and studies. On the graph showing your hydration results is a line marked with zero. This represents the threshold for acceptable hydration, and should be considered the minimum level of hydration your body needs. A measurement above zero is desirable. Each person's zero point is calculated by determining the hydration of their lean mass (everything except fat), plus the water contained in their body fat. Just as physical makeup varies from person to person, so does the zero point 	<p>The predicate device offers the measurement of “hydration” as an additional/alternative physiological parameter. However, this feature does not substantially change the overall design intention of the device and can be considered to be a “marketing” feature. Therefore, Substantially Equivalent</p>
Device Options	<ul style="list-style-type: none"> Printer for results Barcode scanner (2D) Data Ports for Personal Health Devices:-USB: Used for pedometer download., Ethernet Connection: Ability to connect to the HealthChek database though built-in Ethernet port 	<ul style="list-style-type: none"> Printer for results / incentives / coupons Barcode scanner (2D) Personal health device upload ports: IR, USB mini, micro, Type A (Download stations for Omron Pedometers and for blood glucose meters) 32-inch LCD HD display screen (for Advertising, Information and Store messaging) Wi-Fi or cellular connectivity Loyalty Card reader – so customer can access an online account 	<p>In regards to device options, the predicate device allows for the use of a 32” LCD screen which is used for advertising purposes as well as the use of a “loyalty card” which is also a brand-identification feature that does not change the overall indication for use. The proposed device does not include WiFi or cellular connectivity, but does include an Ethernet connection that is used to store patient-data. Unlike the predicate wherein their WiFi / cellular connection is used to transmit data to the personal physician. Allowing the user to conveniently store and retrieve their data is a marketing feature and does not affect patient safety. Therefore, Substantially Equivalent</p>
COMPARISON OF ERGONOMICS/HUMAN FACTORS			
User Input Mechanism	Touch screen interface	17 inch LCD touch screen user navigationBP “Express” feature	Both devices use a touch screen; the size of the screen is immaterial. Therefore, Substantially Equivalent
Data Output / Display Mechanisms	<ul style="list-style-type: none"> On-Screen Display Built-in 200 dpi Printer 	<ul style="list-style-type: none"> On-Screen Display Built-in Laser Printer Loyalty Card reader – so customer can access an online account 	Both devices have on-screen displays and the ability to print out the data. The type of printer and the ability to access the user’s information via a “loyalty card” is immaterial. Therefore, Substantially Equivalent
Data Storage	No data is saved directly on the kiosk. All data is stored remotely.	No data is saved directly on the kiosk. All data is stored remotely	Neither device stores personal data on the kiosk itself although the proposed device is not designed to forward the information on to a personal health care practitioner. Therefore, Substantially Equivalent
COMPARISON OF PATIENT CONTACT MECHANISMS & MATERIALS			
Patient Contact/Interf	Blood pressure cuff is in compliance with ISO 10993	Blood pressure cuff is in compliance with ISO 10993	Both devices are in compliance with the same standard.



**HealthChek Network
Health Station, Model HCK – 2000
Traditional 510(k) Summary - REVISED**

VOLUME 2

SECTION 3

Feature	HealthChek Network Model HCK - 2000 (Health Station System Under Review)	StayHealthy HealthCENTER Biometric Screening Kiosk (Cleared under K123539)	Substantial Equivalence Comments
Case Materials			Therefore, Substantially Equivalent
COMPARISON OF POWER REQUIREMENTS / COMPUTER INTERFACE			
Operating System	Windows Seven	Windows seven (embedded)	Both devices operate on the same Windows platform. The issue of “embeddedness” is immaterial. Therefore, Substantially Equivalent
User Input Mechanism	Touch screen interface	Touch screen user navigationBP “Express” feature	Both devices use a touch screen for user input. Therefore, Substantially Equivalent
Power Source	Single phase 110/220 VAC, 2A 50 or 60 Hz	120V, 60Hz, 2.0A	Both devices can operate on standard USA power inputs. Therefore, Substantially Equivalent
COMPARISON OF DIMENSIONAL SPECIFICATIONS			
Dimensions	32” W x 27.5” L x 62” H	27.5” W x 39.6” L x 44.2” H (80” H with optional LCD display)	Both devices have similar dimensions suitable for use as a public-accessible health kiosk. Therefore, Substantially Equivalent
Weight	230 lbs	200 lbs / 90 KG	Both devices have similar weights that are needed to create a public-accessible health kiosk. Therefore, Substantially Equivalent
COMPARISON OF ENVIRONMENT SPECIFICATIONS			
Operating Environment (overall system)	15° C to +50° C 15 to 95% (Non-Condensing)	41 - 95 °F (5 to 35 °C) 10 - 80% (non-condensing)	Both devices are designed to operate in similar “office-based” environments. Therefore, Substantially Equivalent
Storage Environment	-20° C to +50° C 10 to 90% (Non-Condensing)	Not specified	While not stated/known for the predicate, it is reasonable to assume that both devices have similar storage conditions. Therefore, Substantially Equivalent
COMPARISON OF APPLICABLE STANDARDS			
Quality System Standards Compliance	<ul style="list-style-type: none"> CFR 21CFR820: Part 820 – Quality System Regulations ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes 	FDA-cleared class II medical devices	Both devices claim compliance with similar quality system standards. Therefore, Substantially Equivalent
Safety Standards / Testing Compliance (3 rd party testing conducted)	<ul style="list-style-type: none"> IEC 60601-1:2005 3rd edition General requirements for basic safety and essential performance IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (with immunity testing to 60601-1-2:2014) IEC 80601-2-30:2000 Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers AAMI/ANSI/ISO 81060-1:2013 Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type (via OEM) 	<ul style="list-style-type: none"> UL/IEC 60601-1/2 certified CAN/CSA-C22.2 certified ISO 81060-1:2002 compliant blood pressure device (via OEM) 	Both devices claim compliance with similar safety standards. Therefore, Substantially Equivalent
Design Standards Compliance (Used internally during the design process)	<ul style="list-style-type: none"> ISO 14971:2007 Medical devices - Application of risk management to medical devices 47CFR Part 15 Federal Communications Commission (FCC) 2002/95/EC Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) HIPAA compliant 	<ul style="list-style-type: none"> American Disabilities Act (ADA) compliant HIPAA compliant RoHS compliant 	Both devices claim compliance with similar design standards. Therefore, Substantially Equivalent