January 19, 2022

Solohealth, Inc.
% Jeff Rongero
Third Party Official
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle, North Carolina 27709

Re: K113402
Trade/Device Name: Solohealth Station
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, HOX

Dear Jeff Rongero:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 30, 2012. Specifically, FDA is updating this letter to reflect the correct product code.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Shih Kozen
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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 30 2012

SoloHealth, Inc.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K113402
Trade Name: SoloHealth Station
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Codes: DRG, HOX
Dated: May 24, 2012
Received: May 25, 2012

Dear Mr. Rongero:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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 Statement

510(k) Number (if known): K113402

Device Name: SoloHealth Station

Indications for Use:

The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.

Prescription Use No (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use Yes (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113402

MAY 3 0 2012

510(k) Summary

SoloHealth Station K113402

May 18, 2012

Company: SoloHealth, Inc.
11555 Medlock Bridge, Suite 190
Duluth, GA 30097
Phone: (770) 622-4158
Fax: (770) 622-4122

Establishment Registration: 3007156596

Primary Contact: Kimberly Strohkirch
Memphis Regulatory Consulting, LLC
Phone: (901) 361-2037

Company Contact: Stephen Kendig
Chief Operating Officer

Trade Name: SoloHealth Station

Common Name: Automated Blood Pressure Monitor

Classification: Class II

Regulation Number: 870.1130 – Non-invasive blood pressure measurement system

Panel: Cardiovascular

Product Code: DXN

Device Description:
The SoloHealth Station is an automated system for measuring blood pressure and pulse rate designed to be used by the general public in indoor high-traffic commercial areas. It is completely automatic, and measures blood pressure by the oscillometric method. The user is guided by a series for interactive screen and voice instructions. Additionally, the SoloHealth Station measures weight, screens clarity of central vision, and does a risk factor analysis. Users are advised to consult a physician. Upon completion, data may be stored by the user and accessed via a website or sent via electronic mail to the user.

Indications for use:
The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.

Substantial Equivalence:
The SoloHealth Station is substantially similar to predicate devices currently on the market. These devices are the LifeClinic® 2400 (K040562), Computerized Screening, Inc CSI Model 5k Managed Health System Kiosk (K093389) and Xperex Health Check Kiosk (K063008) as shown in Table 1. The central vision screening of the SoloHealth Station is similar to Accutome Eye Charts, Vimetrics Central Vision Analyzer 1000, and Optec 5000 Series Vision Tester shown in Table 2. The SoloHealth Station has the following main components: Blood Pressure Application, Weight Measuring Application, Vision Test, and Test Results. Biocompatibility for the blood pressure cuff is established utilizing Xperex's Health Check Kiosk (K063008).

Table 1. Detailed comparison of the subject and predicate devices.

	SoloHealth Station	LifeClinic® 2400 (K040562)	Computerized Screening, Inc CSI Model 5k Managed Health System Kiosk (K093389)	Xperex Inc. Health Check Kiosk (K063008)	Comparison
Intended Use	General public to measure blood pressure and pulse rate; Weight measurement and screen clarity of central vision	General public to measure blood pressure and pulse rate; Not a diagnostic device	General public to measure blood pressure and pulse rate; Not a diagnostic device	General public to measure blood pressure and pulse rate; Not a diagnostic device	Similar to LifeClinic 2400, CSI Model 5k and Xperex Health Check Kiosk
Indications for Use	The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only	The Lifeclinic 2400 is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate. It is not a diagnostic device, and only furnished data so that the users can consult their personal physician.	The CSI Model 5K Managed Health System Kiosk is intended for use by the general public to measure blood pressure, pulse and weight. It is not intended to be a diagnostic device; it only provides data on blood pressure, heart rate and weight and users are advised to consult a physician.	The Health Check Kiosk is intended to be used by the general public so that a user can measure health parameters such as weight, body fat, blood pressure and pulse rate in public places and/or corporate environments. It is not for diagnostic use.	Similar to LifeClinic 2400, CSI Model 5k and Xperex Health Check Kiosk

	SoloHealth Station	LifeClinic® 2400 (K040562)	Computerized Screening, Inc CSI Model 5k Managed Health System Kiosk (K093389)	Xperex Inc. Health Check Kiosk (K063008)	Comparison
	screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.				
Intended Population	General Public	General Public	General Public	General Public	Identical
Human Factors	Shock Hazard tested per IEC 60601-1:1988 and IEC 60601-2-30:1999; Blood Pressure Risks tested per AAMI SP10	Blood Pressure Risks tested per AAMI SP10	Blood Pressure Risks tested per AAMI SP10	Not available	Risks addressed per current industry standards
Hardware Design	LCD Interface to control blood pressure and pulse rate measuring device. A stop button stops the blood pressure rate and measuring device.	Start/stop button to control blood pressure and pulse rate measuring device	LCD Interface to control blood pressure and pulse rate measuring device	Start/stop button to control blood pressure and pulse rate measuring device	SoloHealth Kiosk uses an LCD screen as opposed to directions on the device for the user to control the device. A stop button stops the blood pressure rate and measuring device. No additional risks for control method.
Software Design	The SoloHealth Station uses software as an automated system for measuring blood pressure and pulse rate. It is completely automatic, and measures blood pressure by the	The Lifeclinic 2400 uses software as an automated system for measuring blood pressure and pulse rate. It is completely automatic, and measures blood pressure by the	The CSI 5k Kiosk uses software as an automated system for measuring blood pressure and pulse rate. It is completely automatic, and measures blood pressure	Xperex Health Check Kiosk uses software as an automated system for measuring blood pressure and pulse rate. It is completely automatic, and measures blood pressure by the	The software program used by the predicate is not available for direct comparison. However, both systems provide blood pressure measurements in an automatic way using software.

	SoloHealth Station	LifeClinic® 2400 (K040562)	Computerized Screening, Inc CSI Model 5k Managed Health System Kiosk (K093389)	Xperex Inc. Health Check Kiosk (K063008)	Comparison
	oscillometric method. The user is guided by a series of interactive screens and voice instructions.	oscillometric method. The user is guided by a series of interactive screens and voice instructions.	by the oscillometric method. The user completes functions by pushing labeled buttons.	oscillometric method. The user is guided by a series of interactive screens and voice instructions.	
Dimensions and Weight	2 ft wide x 3 ft deep x 5 feet tall	Not available	Not available	Not available	Dimensions of predicate devices are not available for comparison.
Performance Standards Met	AAMI Standards IEC Standards	AAMI Standards	AAMI Standard IEC Standards	AAMI Standards	Identical AAMI Standards. SoloHealth Kiosk also meets Electrical Safety Standards.
Materials	Commercially available materials including soda lime glass for touchscreen, metal housing, and latex-free polyester thread for cuff	Not available	Not available	Latex-free polyester thread for cuff. The rest of the material is not available.	Materials of predicate not available for comparison. Materials of SoloHealth Station currently commercially available.
Cleaning/Disinfection/Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Identical
Biocompatibility	Commercially available materials including soda lime glass for touchscreen, metal housing, and latex-free polyester thread for cuff. Blood pressure cuff is identical to cuff used in Xperex	None listed in 510(k) Summary	None listed in 510(k) Summary	None listed in 510(k) Summary	Materials of SoloHealth are widely available commercially and do not necessitate biocompatibility testing.

	SoloHealth Station	LifeClinic® 2400 (K040562)	Computerized Screening, Inc CSI Model 5k Managed Health System Kiosk (K093389)	Xperex Inc. Health Check Kiosk (K063008)	Comparison
	Corp's Health Check Kiosk.				
Electromagnetic Compatibility	Meets IEC 60601-1-2:2001	None listed in 510(k) Summary	Meets IEC 60601-1-2	None listed in 510(k) Summary	The SoloHealth Station is tested to meet electromagnetic compatibility requirements.
Components	Blood Pressure and Pulse Rate; Weight; Vision	Blood Pressure and Pulse Rate	Blood Pressure and Pulse Rate; Weight	Blood Pressure and Pulse Rate	The SoloHealth Station has additional functionality of vision screening via standard eye chart, which is not a medical device.
User Interaction	Interactive screens and voice instructions	Interactive screens and voice instructions	Push buttons	Interactive screens and voice instructions	Identical to LifeClinic 2400

Table 2. Similar Vision Screening Devices.

	Subject Device	Similar Vision Screening Devices			
	SoloHealth Station	**Eye Chart**	**Vimetrics Central Vision Analyzer 1000 (CVA-1000)**	**Optec 5000 Series Vision Tester**	**Detailed Comparison**
510(k)	Subject Device K113402	None	K100095	None located	Comparison not applicable.
Manufacturer	SoloHealth	Accutome	Vimetrics, LLC	Stereo Optical	
Establishment Registration	3007156596	2521877	None found in FDA database	1419226	
Primary Device Listing	DXN, Automated Blood Pressure Monitor HOX, Chart, Visual Acuity	HOX, Chart, Visual Acuity	HOX, Chart, Visual Acuity	HOX, Chart, Visual Acuity; HIT, Tester, Vision Color	The SoloHealth Station central vision screening is similar to the visual acuity chart of the Eye chart, Central Vision Analyzer and Optec 5000.
Classification	Class II	Class I Exempt	Class I, requiring premarket notification	Class I Exempt	The SoloHealth Station is Class II and is subject to 510(k) clearance. The vision screening component of the SoloHealth Station is similar to the Eye Chart, Central Vision Analyzer, and Optec 5000 that are Class I.
Intended Use	General public to measure blood pressure and pulse rate; Weight measurement and screen clarity of central vision	To test visual acuity	The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.	To test visual acuity	The SoloHealth Station is similar to all similar devices and is intended to screen for clarity of central vision.
Indications	The SoloHealth Station	No labeling	The OVA-1000 is intended	No labeling	The indication for screening

	Subject Device	Similar Vision Screening Devices			
	SoloHealth Station	**Eye Chart**	**Vimetrics Central Vision Analyzer 1000 (CVA-1000)**	**Optec 5000 Series Vision Tester**	**Detailed Comparison**
	is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.	available	for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.	available	for clarity of central vision is the same intent and is similar to the indications statement by Central Vision Analyzer. The SoloHealth Station does measure vision at fixation in one or both eyes with or without optical correction in central vision as does the predicate Central Vision Analyzer.
Intended Population	General Public	General public	General Public with supervision of ophthalmologist or optometrist	General Public	Similar to the Optec 5000, the SoloHealth Station is intended for the general public use. The Optec 5000 is used by department of transportation to test visual

	Subject Device	Similar Vision Screening Devices			
	SoloHealth Station	**Eye Chart**	**Vimetrics Central Vision Analyzer 1000 (CVA-1000)**	**Optec 5000 Series Vision Tester**	**Detailed Comparison**
					acuity by the general public. The kiosk predicates are also intended for the general public.
Near Distance Screening	Yes; Screening simulated at 17 inches	Yes	Yes	Yes; Screening simulated 16 in.	All devices are used for near distance screening.
Far Distance Screening	Yes; Screening simulated at 11 feet	Yes	Yes	Yes; Screening simulated 20 feet	All devices are used for far distance screening.
Display/Technology	LCD computer monitor, UL 60950 Interactive Central Vision Panel	Plastic chart	Yes, LCD computer monitor and interactive central vision panel	LED lighted films	The SoloHealth Station uses an LCD computer monitor and interactive central vision panel which is substantially equivalent to the predicate of Central Vision Analyzer.

Performance Testing:

Performance testing of the SoloHealth Station consists of performance testing, safety testing, electromagnetic testing, and software validations.

Software validation has been satisfactorily completed according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) and "Non-invasive Blood Pressure (NIBP) Monitor Guidance" (March 10, 1997) for a device of moderate concern. Hardware of the SoloHealth Station includes a computer with Microsoft Windows 7 Operating system with 4 GB RAM, Intel i5 650 Processor, and a 20 GB Hard Drive. Software requires the following applications: .Net framework v4.0, Logmein Pro2 v4.1 or higher, ELO Touch screen drivers, Apache Server, MySql, and Firefox portable. Device Risk Hazards Analysis, Software Requirements Specification Architecture Design Chart, Software Design Specifications, Traceability Analysis, Software Development Environment Description, and Revision History were completed in accordance with the guidance documents.

Electromagnetic compatibility testing was completed and passed in accordance with IEC 60601-1-2:2001. Electrical safety testing was completed in accordance with IEC 60601-1:1988 and IEC60601-2-30:1999. Several clauses indicated failures initially. These clauses were re-tested resulting in satisfactory results or justification that the clauses were not applicable to the SoloHealth Station, which is located in an indoor environment.

Electromagnetic testing was performed on the SoloHealth Station and passed per the following standards:

- IEC 60601-1-2:2001, 2nd Ed Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Electromagnetic Compatibility

Safety testing was performed on the SoloHealth Station and passed per the following standards:

- IEC 60601-1:1988+A1:1991+ A2:1995 Medical Electrical Equipment Part 1-2: General Requirements for Safety
- IEC 60601-2-30:1999, Particular Requirements for Safety, including essential performance, of automatic cycling non-invasive blood pressure measuring equipment

Performance testing was performed on the SoloHealth station and passed per the following standards:

- AAMI/ANSI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(Manual, electronic or automated sphygmomanometers

Bench testing for AAMI SP10 was completed separately by the supplier of the blood pressure module. Verification testing performed by the supplier ensures compliance with AAMI SP10 for the blood pressure cuff. Both of these components are not altered when assembled in the SoloHealth Station.

Clinical testing according to AAMI SP10 was completed by the supplier of the blood pressure module on the module itself. The module is not altered when assembled in the SoloHealth Station. Full AAMI SP10 testing protocol was executed in Duluth, GA on the final device design and has shown that the SoloHealth Station kiosk demonstrates compliance to AAMI SP10. Additionally, confirmatory testing was completed with the SoloHealth Station on a limited number of subjects to ensure that the use of an alternate cuff does not affect the results as compared to the AAMI SP10 testing on the module.

Vision Screening Validation of the SoloHealth Station demonstrates that the screenings of the SoloHealth Station are similar to a licensed Optometrist.

In conclusion, the performance testing, safety testing, electromagnetic testing, and software validations according to the industry standard shows that the SoloHealth Station is substantial equivalent to the predicate devices and assures that the SoloHealth Station is as safe and effective as the predicate devices.