K101198
p1/3

510(k) Summary

(per 21 CFR 807.92)

AUG 0 4 2010

I. Applicant

Computerized Screening, Inc.
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Reno, NV 89521
USA

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II. Device Name

Trade Name: CSI Model 9K Managed Health System
Common Name: Automated noninvasive blood pressure monitor
Classification Name: Noninvasive blood pressure measurement system
Classification Number: 870.1130
Product Code: DXN
Subsequent Product Codes: FLL
Classification: Class II

III. Predicate Devices

K093389: CSI Model 5K
K090294: ForaCare IR22 Digital Thermometer
K063008: Health Check Kiosk

The blood pressure, weight and pulse measurement systems used in Model 9K is exactly the same as the one used in the CSI Model 5K. The CSI Model 9K uses the same thermometer as the ForaCare IR22. The CSI 9K and predicate device Xperex Health Check Kiosk have the same general use to measure health parameters.

IV. Intended use of the Device

CSI Model 9K Managed Health System Kiosk is an automated non invasive screening device intended for voluntary use by the general public. The device measures systolic and diastolic blood pressure, pulse and if optionally equipped, weight and temperature. Users may also manually enter or download blood glucose level. Data from the Model 9K may be

stored by the user for tracking purposes. It is not a diagnostic device, and only furnishes data so users can consult their personal physicians.

The device is intended for users fourteen years or older. Children under the age of fourteen must be accompanied by an adult.

V. Description of the Device

The CSI Model 9K Managed Health System Kiosk provides an unsupervised means for measuring and tracking an individual's blood pressure (both systolic and diastolic) and pulse rate. The kiosk can typically be installed in corporate lobbies and can be part of corporate wellness programs to track changes over time.

The device has a touch screen for user interface. The user may select from a menu of items. For instance, touching the button "Blood Pressure" on the touch screen will result in a sub menu that will direct the user to insert the arm in the cuff mechanism before pressing the "Start" button on the touch screen. The unit also consists of a "Release" push button that is separate from the touch screen. This "Release" button would result in the immediate deflation of the cuff and the aborting of the test. This well marked red button is meant for use in the event of an emergency. Other buttons on the main menu of the touch screen display would result in the user receiving the blood pressure (systolic and diastolic), heart rate, weight and temperature readings.

In addition to measuring the user's blood pressure, weight and temperature, the 9K may also be capable of accepting uploaded data from a One Touch Ultra Glucometer and playing videos on health topics. Data measured by the 9K or input into the 9K can be stored for tracking purposes. The 9K may also have the ability to display websites like WebMD, MayoClinic and corporate portals. Videos may present medical information and present symptoms but not diagnoses. The 9K may also be equipped with a scanner, printer, finger print reader and signature pad.

VI. Technical Characteristics

The CSI Model 9K Managed Health System Kiosk measures systolic and diastolic arterial blood pressure using an inflatable cuff mechanism that is placed around the user's arm. The cuff is then inflated before it is gradually deflated through a series of controlled deflation steps (Oscillometric method). While the user interface is provided by a remote server, the blood pressure testing is totally controlled by the BPM controller with only the hardware "Release" button having override authority. The software and graphics are held on the server and sent to the unit based on the user input. When the user requests a blood pressure test

using the touch screen, the server sends a request and cedes control to the BPM controller and waits for the readings to be returned. A similar process occurs with the weight and temperature measurement.

Substantial Equivalence: The CSI 9K is a combination of the CSI model 5K and the Fora Care model IR22. The CSI model 9K performs the blood pressure, pulse rate and weight measurement in substantially the same way with substantially the same electronics producing substantially the same results as the CSI model 5K. In addition, the CSI model 9K incorporates the ForaCare model IR22 thermometer as part of the system.

The CSI 9K and predicate device Xperex Health Check Kiosk have the same general use to measure vital signs of a user for display. According to the Device Description presented in the summary of the 510(k) filing for the Health Check Kiosk, "...is erected in public spaces, and provides a location where the general public can measure various health parameters using devices cleared for use...". The Xperex unit's intended use is as "...a multi-functional unit that provides tests for the general public to measure personal health parameters...".

VI. Testing

CSI Model 9K Managed Health System Kiosk has been subjected to clinical evaluation and bench testing and meets the requirements of AAMI/ANSI SP10:2002. The device also meets the IEC 60601-1 standard for Medical Electrical Equipment – General requirements for safety, IEC 60601-1-1 for Medical Electrical Equipment, General Requirements for Safety – Collateral Standard, IEC 60601-2-30 Particular requirements for safety including essential performance and 60601-1-2 EMC Standards for electrical medical equipment. The cuff and the thermometer are certified to be compliant with ISO 10993.

VII. Date of Preparation

This 510(k) Summary was prepared on July 28, 2010.

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

AUG 0 4 2010

Computerized Screening, Inc.
co Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K101198
Trade/Device Name: CSI Model 9K Managed Health System
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 16, 2010
Received: July 19, 2010

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

K101198

Indications for Use

510(k) Number (if known): _____ AUG 0 4 2010

Device Name: CSI Model 9K Managed Health System

Indications for Use:

CSI Model 9K Managed Health System Kiosk is an automated non invasive screening device intended for voluntary use by the general public. The device measures systolic and diastolic blood pressure, pulse and if optionally equipped, weight and temperature. Users may also manually enter or download blood glucose level. Data from the Model 9K may be stored by the user for tracking purposes. It is not a diagnostic device, and only furnishes data so users can consult their personal physicians.

The device is intended for users fourteen years or older. Children under the age of fourteen must be accompanied by an adult.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (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 (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101198