K093389
p1/2

510(k) Summary

(per 21 CFR 807.92)

NOV 17 2009

I. Applicant

Computerized Screening, Inc.
9550 Gateway Drive
Reno, NV 89521
USA

Contact: Sam Kumar
Vice President of Manufacturing Operations
Tel: (775) 359-1191
Fax: (775) 359-7879
Email: skumar@computerizedscreening.com

II. Device Name

Trade Name: CSI Model 5K Managed Health System Kiosk
Common Name: Automated noninvasive blood pressure monitor
Classification Name: Noninvasive blood pressure measurement system
Classification Number: 870.1130
Product Code: DXN
Classification: Class II

III. Predicate Devices

K063137: PharmaSmart, Model PS-1000/PS-1500/PS-2000
K040562: HealthGuard International, Lifeclinic 2400

IV. Intended use of the Device

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.

V. Description of the Device

The CSI Model 5K 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 retail establishments and drug stores and may or may not be part of the pharmacy.

The device has push buttons for user interface. Such buttons include "Start" button to start the test after the user has inserted the arm into the cuff mechanism, a "Release" button to deflate the cuff mechanism in the event of an emergency, a "Weight" button to start the process of measuring the weight of the user. The output of the machine includes displays to indicate the blood pressure (systolic and diastolic), heart rate and weight.

To start the process, the user inserts her arm into the cuff and pushes a button. The machine then proceeds to inflate the cuff and measure the blood pressure using oscillometric method. Once measured, the blood pressure (both systolic and diastolic) and the heart rate are output to the display mounted on the front of the device.

VI. Technical Characteristics

The CSI Model 5K 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).

VI. Testing

CSI Model 5K 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 and 60601-2-30 standard for Medical Electrical Equipment Part 2 Particular Requirements for Safety and 60601-1-2 General Requirements for Safety, Electromagnetic Compatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Computerized Screening, Inc.
c/o Mr. Morten Christensen
Staff Engineer, Reviewer
Underwriters Laboratories, Inc.
455 E. Trimble Road,
San Jose, CA 95131

NOV 17 2009

Re: K093389
Trade/Device Name: CSI Model 5K Managed Health System Kiosk
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: September 10, 2009
Received: October 30, 2009

Dear Mr. Christensen:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093389

Indications for Use

510(k) Number (if known): _____

Device Name: CSI Model 5K Managed Health System Kiosk

Indications for Use:

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.

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 K093389

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