DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 17, 2017

H4D SAS
% Esin Yesilalan
Senior Regulatory Scientist
Voisin Consulting Life Sciences
222 Third Street
Suite 3121
Cambridge, Massachusetts 02142

Re: K153600
Trade/Device Name: Consult Station TS
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, FLL, DQA
Dated: February 27, 2017
Received: February 28, 2017

Dear Esin Yesilalan:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153600

Device Name
Consult Station TS

Indications for Use *(Describe)*
The Consult Station TS is intended to be used by the general public to perform a health check, including the measurement of certain vital signs (weight, BMI, temperature, blood pressure and pulse rate). The lay user autonomously self-performs all the measurements listed above.

Using an audio-video conferencing feature incorporated in the Consult Station TS to connect with a healthcare professional remotely, it is possible to perform additional examinations: ENT (Ear, Nose, Throat) and skin examinations, auscultations sounds and blood oxygen level. The lay user and the healthcare professional are able to see and to interact each other.

The Consult Station TS is not intended for diagnostic use. Lay users should consult their personal physician if they have concerns regarding the results of their health check.

The Consult Station TS is intended for lay users of fourteen (14) years old or older. The Consult Station TS is not intended for children under the age of fourteen.

The Consult Station can be deployed in indoor public areas, such as: pharmacies, senior living communities, shopping centers, corporations, etc.

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.

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SECTION 5
510 (k) SUMMARY

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5 510(K) SUMMARY

5.1 Submitter Information

Company Name:	H4D
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Contact Person:	Marta Rivas
Date of Summary:	February 24, 2017

5.2 Device Identification

Trade Name:	Consult Station TS ®
Common Name:	Health booth
Classification Name:	Non-invasive blood pressure measurement system
Product Code:	DXN, FLL, DQA
Regulation Number:	870.1130
Device Class:	Class II

5.3 Identification of Predicate Devices

H4D's Consult Station TS® is substantially equivalent to the following predicate device:

- *CSI Model 9K Managed Health System*, manufactured by Computerized Screening, Inc. and cleared for commercial distribution under 510(k) K101198;

Among the FDA Class II device components of the Consult Station, the non-invasive blood pressure module and the thermometer carry a CE approval in the EU; however, they are not cleared in the US. Nevertheless, this blood pressure module is substantially equivalent to Omron Hem-705CP Automated Monitor System (510(k) K903134) and the temperature module is equivalent to Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10) (510k number K160816).

- *Omron Hem-705CP* Automated Monitor System 510(k) K903134;
- *Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)* (510k number K160816).

5.4 Device Description

The Consult Station TS is an automated non-invasive screening device intended to be used by the general public (lay users). Equipped with sensors and instruments, the Consult Station TS presents itself in the shape of a health booth and allows to perform health check-ups in order to collect reliable medical data.

The Consult Station TS is not a diagnostic device and only provides data in order for lay users to consult with their personal physician. Lay users should consult with their physician if they have concerns regarding the results of their health check-up.

Two scenarios for the use of the Consult Station TS are available:

1. A scenario where the lay user will autonomously self-perform the measurements of his/her vital signs ("Unsupervised Mode");

   This use does not require assistance of a healthcare professional. The lay user autonomously self-performs a health check allowing him/her to collect a number of his/her vital signs: weight and BMI, systolic and diastolic blood pressure, pulse rate and temperature. An user interface guides the lay user with video tutorials, a series of interactive screens and voice instructions through the various steps of the health check cycle.

2. An alternative scenario where, at first, the lay user will autonomously self-perform measurements of his/her vital signs ("Unsupervised Mode"), and then be remotely connected with a healthcare professional through the audio-video conferencing feature to perform additional examinations ("Supervised Mode").

   This use that requires assistance of a healthcare professional to ensure that data is appropriately collected and interpreted. After performing a health check (see scenario above), the lay user is connected through the audio-video conferencing feature with a healthcare professional, the lay user and the healthcare professional being able to see and to interact with each other.

   The healthcare professional can then remotely guide the lay user to use as needed:
   - an otoscope for ENT examinations (inspection of the external ear canal),
   - a dermatoscope for skin surface examinations,
   - a stethoscope for auscultation of sounds associated with the heart and lungs,
   - a pulse oximeter for the measurement of the blood oxygen level.

The otoscope (ENT examination), the dermatoscope (skin examination), the stethoscope (auscultations sounds) and the pulse oximeter (blood oxygen level) are only used in the Supervised Mode. The use of the pulse oximeter, dermatoscope, otoscope and the stethoscope are restricted on the order of a licensed practitioner.

In both scenarios, at the end of cycle, a ticket is printed inside the booth which summarizes the results of the measurement as well as user access codes for subsequent online access.

Lay users may manually enter blood glucose level measurements. The Consult Station TS may accept loaded data from an external blood glucometer (if such device is FDA cleared).

Consult Station is intended for users of 14 years old or older. The Consult Station TS is not intended for children under the age of fourteen (14).

Consult Station TS system consists of:

- A health booth,
- A software embedded in the health booth,
- A Consult Access software containing an audio-video conferencing feature,
- A web application which provides secure access by patients and health professionals to their anonymized data.

The **health booth** is an enclosed space, accessible through a door and containing a seat, sensors and instruments as well as communication tools (i.e. screens, camera, speakers, printer).

The **software embedded** in the health booth is responsible for the management of the man-machine interface (MMI) used to provide instructions to the patient, to collect patient data and to print them via the printer on a ticket. The software is also responsible for starting, stopping and repeating measurements. These functionalities are implemented by communicating via the serial or USB interfaces of the connected devices involved (sending commands followed by receiving of results).

The **Consult Access** is a software that allows through an **audio-video conferencing** connecting a healthcare professional with a patient seated inside the Consult Station. The patient and the healthcare professional will be able to see and to interact with each other. The healthcare professional can remotely guide the patient throughout all the measurements and examinations performed. The otoscope, the dermatoscope and the oximeter are only available while the video conferencing feature is in use.

The **web application** provides secure access by patients and healthcare professionals (only with the patient's agreement) to the measurements performed via the Consult Station TS.

5.5 Indications for Use

The Consult Station TS is intended to be used by the general public to perform a health check, including the measurement of certain vital signs (temperature, weight and BMI, blood pressure and pulse rate). The lay user autonomously self-performs all the measurements listed above.

Using an audio-video conferencing feature incorporated in the Consult Station TS to connect with a healthcare professional remotely, it is possible to perform additional examinations: ENT (Ear, Nose and Throat) and skin examinations, auscultation sounds and blood oxygen level. The lay user and the healthcare professional are able to see and to interact with each other.

The Consult Station TS is not intended for diagnostic use. Lay users should consult their personal physician if they have concerns regarding the results of their health check.

The Consult Station TS is intended for lay users of fourteen (14) years old or older. The Consult Station TS is not intended for children under the age of fourteen (14).

The Consult Station TS can be deployed in indoor public areas, such as: pharmacies, senior living communities, shopping centers, corporations, etc.

5.6 Comparison to Predicate Devices

H4D is claiming substantial equivalence for Consult Station TS with the CSI Model 9K Managed Health System, which is currently commercially available in the U.S. Relevant information on the predicate devices is shown in Table 5-1.

Table 5-1 Table Predicate Devices for Consult Station TS®

Device Name	CSI Model 9K Managed Health System
Manufacturer	Computerized Screening, Inc.
510(k) Number	K101198
Regulatory Class	Class II
Common Name	Automated Blood Pressure Monitor
Clearance Date	04 Aug 2010

H4D is claiming substantial equivalence for the blood pressure module with the Omron Hem-705CP, which is currently commercially available in the U.S. Relevant information on the predicate devices is shown in Table 5-1

Table 5-2 Table Predicate Devices for the blood pressure module

Device Name	Omron Auto Oscillometric DIG BP MONT/HEM-704C 705C
Manufacturer	Omron Marshall Products, INC.
510(k) Number	K903134
Regulatory Class	Class II
Common Name	Noninvasive blood pressure measurement system
Clearance Date	01/08/1991

H4D is claiming substantial equivalence for the temperature with the Infrared thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10) which are currently commercially available in the U.S. Relevant information on the predicate devices is shown in Table 5-3.

Table 5-3 Table Predicate Devices for the thermometer

Device Name	Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)
Manufacturer	Nexmed Technology Co., Ltd
510(k) Number	K160816
Regulatory Class	Class II
Regulation Name	Clinical Electronic Thermometer
Clearance Date	09/21/2016

5.6.1 Summary of Technological Characteristics

The physiological parameters measurements available in Unsupervised Mode (the scenario where the lay user autonomously self-performs all measurements of his/her vital signs) are :

- The weight and BMI calculation,
- The temperature,
- The blood pressure and pulse rate.

The associated instruments for physiological parameters measurement consist of the following:

- An electronic scale,
- An infrared non-contact forehead thermometer,
- An electronic sphygmomanometer.

The exams available in Supervised Mode (the scenario where the lay user remotely connected with a healthcare professional through the audio-video conferencing feature to perform additional examinations) are:

- ENT examinations (inspection of the external ear canal) using an otoscope,
- Skin surface examinations using a dermatoscope,
- Auscultation of sounds associated with the heart and lungs using a stethoscope,
- Blood oxygen level measurement using a pulse oximeter.

The **Hardware computer components** consist of the following:

- Height measuring device using ultrasonic;
- A touch screen which allows to enter data or to answer questions and the start and stop the measurements ;
- An embedded computer with interface connections for sensors and instruments;
- Environmental sensors (temperature, humidity percentage) ;
- A printer ensuring the editing of a ticket which summarizes the measurement results and the patient identifiers.

The **Remote Monitoring components** consist of the following:

- A camera and loudspeakers ;
- A touch screen used as input device for the lay user. Measurements can be started and stopped bylay users using the controls displayed on the touch screen;
- A LCD 19" screen for man-machine interface. The LCD screen is used for displaying interactive screens, videos instructions and measurement results. The functionality to gain remote access to a qualified physician is available via a LCD screen. Once measurements are done (note: the proprietary software of the instruments take over the Consult Station TS during that time) the results are displayed on a LCD screen.

The **Software solution** consists of the following:

- A software embedded in the Consult Station for starting, stopping and repeating measurements, management of the MMI used to give instructions to the patient, to collect patient data and to print them on the printer;
- An audio-video conference feature through which users are remotely connected with a healthcare professional;
- A website, on which users and physicians can consult the medical data collected, through the use of a secure user ID and password (found on the ticket printed inside the booth).

Software requires the following technologies/environments:

- .NET C# Language (Visual Studio 2013, framework 4.5) with WPF, WCF, Entity framework and ASP.NET MVC 2
- MS SQL Server 2012 database server
- IIS 7.5 web server"

Hardware of the Consult Station TS includes a computer with Microsoft Windows 7 Operating system with a Single Board Industrial Computer PCM-9363 with Embedded Intel Atom N455 1.66 GHz/D525 1.8 GHz Processor.

5.6.2 Electromagnetic Compatibility and Electrical Safety

The Consult Station TS has been subject to electromagnetic compatibility and electrical safety and essential performance testing and is compliant with the standards as listed below:

- IEC 60601-1 :2005 + A1 :2012 and AAMI ANSI ES60601-1:2005 and A1:2012 and A2:2010 Electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-11 Edition 1.0 2010-04 Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in homecare environment;

- Consult Station TS meets requirements of compliance with the standard IEC 60601-1-2 Edition 3: 2007-03; Electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests and by equivalence with the standard IEC 60601-1-2 Edition 3: 2007

- Acceptance tests for the home environment and US deviations have been completed according to ANSI/AAMI/IEC 60601-1-:2014 Electrical Safety Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetidisturbances -- Requirements and test.

5.6.3 Performance and Clinical Testing

The Consult Station TS has been subject to bench and clinical evaluation and meets requirements for the basic safety and essential performance of all its components as listed below:

Automated non-invasive sphygmomanometers

- The automated sphygmomanometer has been subject to bench tests and meets requirements of compliancewith the standard ANSI AAMI ISO 80601-2-30:2009 & A1:2013, Particular Requirements for Safety, including essential performance, of automatic cycling non-invasive blood pressure measuring equipment;

The automated sphygmomanometer has been also subject to clinical tests by their original manufacturer before their integration in the Consult Station TS and meets requirements for Clinical and Performance testing according to EN 1060-4: 2004 Non-invasive sphygmomanometers - Part 4 (Procedures for determining the accuracy of the entire automated non-invasive blood pressure system was completed by the supplier of the blood pressure module). The study was completed according to EN ISO 1060-4, as per procedure “Sequential blood pressure measurement” (N3). The methodology, criteria and results of the test meet the compliance with the standard ANSI/AAMI/ISO 81060-2 as per procedure “Same arm sequential method”.

Infrared thermometer

- The IR thermometer has been tested on bench and is compliant with the standard ASTM E1965-98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature;
- The IR thermometer has been subject to clinical investigation and is compliant with the standard ISO 80601-2-56 First Edition 2009-10-01 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

Pulse oximeter

- The pulse oximeter has been subject to clinical tests by their original manufacturer before their integration in the Consult Station TS and meets requirements for Clinical testing according to ISO 80601-2-61 First edition 2011-04-01 Medical electrical equipment - Part 2-61 (Particular requirements for basic safety and essential performance of pulse oximeter equipment was completed according to its original 510(k) (K140785)

Software

Software validation has been satisfactorily completed according to "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (May 11, 2005) for a device of Moderate level of concern. Software Requirements Specification, Architecture Design Chart, Software Design Specifications, Traceability Analysis, Software Development Environment Description, Verification and Validation and Revision Level History were completed in accordance with relevant FDA guidance documents and with the international standard IEC 62304: 2006 Medical device software - Lifecycle software process.

5.6.4 Clinical Studies

An Usability Study, containing 48 U.S. participants in the human factors testing, was conducted by a third part Connected Healthcare Solutions. The H4D Human Factors validation protocol considered and tested various Use Cases, Risks, Known Use Errors and Expert Analysis of hazards and risks associated with use of the devices on forty-eight (48) distinct test subjects in three (3) distinct User groups in a total of ninety-six (96) Unsupervised and Supervised sessions over a period of approximately two (2) weeks of live, observed and documented testing.

The study poplation was allocated in 3 user groups:

- Lay user patients: Male and female ages ≥ 14 – 21 years of age
  - o Patients under the age of 18 had parental consent.
- Lay user patients: Male and female ages 21 years of age and older
- Health Care Professionals

The **primary study** objective was to evaluate the usability of the Consult Station TS:

- System usability by patients was assessed using a quantitative usability instrument and semi-structured one-on-one interviews.
- System functionality was assessed through semi-structured one-on-one interviews and Health Care Provider's feedback in terms of successful vital signs collections.
- Patient compliance using the system was assessed through number of prescribed actions versus actual actions.

The **secondary study** objective was to evaluate the human factors utility of the Consult Station TS:

- System human factors was assessed using a qualitative, subjective instrument and one-on-one interviews.

5.6.5 Biocompatibility Testing

The Consult Station TS has been evaluated in accordance with international and FDA recognized standard, ISO 10993-1 as well as FDA's 510(k) Memorandum G95-1. The Consult Station TS medical components are considered surface devices with skin contact and limited duration. Accordingly, the following biocompatibility tests have been conducted:

- Cytotoxicity according to ISO 10993-5
- Sensitization according to ISO 10993-10
- Skin Irritation according to ISO 10993-10

All tests were performed on sterilized finished product in accordance with Good Laboratory Practices (GLP) with no deviations. These regulations set forth the minimum basic requirements for study conduct, personnel, facilities, equipment, written protocols, operating procedures, study reports, and a system of quality assurance oversight for each study to help assure the safety of FDA regulated products.

5.6.6 Comparison with the Predicates and Conclusion

This paragraph describes the substantial equivalence between the Consult Station TS and the predicates CSI Model 9K Managed Health System (K101198).

Among the FDA Class II device components of the Consult Station, the non-invasive blood pressure module is substantially equivalent to Omron Hem-705CP Automated Monitor System (510(k) K903134).The table 5-5 compares the module with Omron Hem-705CP.

Similarly, thermometer component of the Consult Station TS is manufactured by H4D is substantially equivalent to Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10) (510k number K160816). The table 5.6 compares the thermometer module with Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10) (510k number K160816).

5.7 Device Comparison Table

Table 5-4 compares the similarities and differences between Consult Station TS device and the predicate CSI Model 9K Managed Health System (K101198).

Table 5-4 Device Comparison Table

	Consult Station TS® (subject 510(k))	**CSI Model 9K Managed Health System (K101198)**	**Comparison**
FDA Product Code	DXN, FLL, DQA	DXN	Same (unchanged) CSI Model 9K
Regulation No.	21 CFR 870.1130 (Non-invasive blood pressure measurement system)	21 CFR 870.1130 (Non-invasive blood pressure measurement system)	Same regulation number (unchanged) CSI Model 9K
Device Class	Class II	Class II	Same device class (unchanged) CSI Model 9K
Intended Use	Consult Station TS is an automated non-invasive screening device intended to be used by the general public. It is not a diagnostic device and only furnishes data so users can consult their personal physician. User should consult their personal physician if they have concerns regarding their measurement. The Consult Station TS covers two primary functions: • It allows a lay user to autonomously self-perform the measurement of his/her vital signs (temperature, weight and BMI calculation, blood pressure, pulse rate). • It offers a lay user the possibility to connect via an audio-video conferencing feature with a healthcare professional remotely connected, the lay user and the healthcare professional being able to see and to interact with each other. The healthcare professional will then be able to conduct additional examinations: ENT (Ear, Nose and Throat) and skin examinations, auscultation of heart and lungs sounds and measurement of blood oxygen level and guide the lay user to use the instruments for his/her examination. The healthcare professional will also be able to analyze the readings from these	Unsupervised means for measuring and tracking an individual's blood pressure, pulse rate, and if optionally equipped, weight and temperature. Users may manually enter or download blood glucose level.	**<u>Unsupervised Mode:</u>** The Consult Station TS has the same intended use (i.e. furnishes medical data so lay users can consult their personal physician) and follows the same principles of operation (i.e. self-performing health check-ups via an automated non-invasive device in the form of a health booth with panels, windows, door and seat) as the predicates. Both the Consult Station TS and CSI Model 9K measure systolic and diastolic blood pressure, pulse rate and (if optionally equipped for CSI Model 9K) weight and temperature. Lay users may also manually enter or download blood glucose level with both devices. **<u>Supervised Mode:</u>** When using the audio-video conferencing feature, the Consult Station TS integrates additional instruments (pulse oximeter, stethoscope, otoscope and dermatoscope) to perform specific examinations (ENT and skin examinations, auscultation sounds and blood oxygen level) not made available with the

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
	examinations. Lay users may also download blood glucose level provided by an external glucometer (not integrated in the booth, (if such device is FDA cleared).). Upon completion, data may be stored and accessed by the user via a website. Consult Station is intended for users fourteen years or older. The Consult Station TS is not intended for children under the age of fourteen. The use of the pulse oximeter, dermatoscope, otoscope and the stethoscope are restricted on the order of a licensed practitioner. Users may manually enter or download blood glucose level.		predicates. Use of these supplementary functionalities requires guidance of a physician via audio-conferencing to ensure that medical devices are properly placed on the lay user and data is appropriately collected for interpretation by the physician. The selected pulse oximeter (K140785) and stethoscope (K102893) are FDA cleared for "remote use by a physician using a computer" as they are intended to be used when integrated into the Consult Station TS. Addition of the oximeter does not affect the safety and effectiveness of the Consult Station TS. The stethoscope is FDA cleared, 510(k), K102893. The otoscope/ dermatoscope are MD class I, FDA exempt. The addition of the stethoscope electronic, otoscope/dermatoscope does not raise new questions in terms of safety /effectiveness of the Consult Station TS. Consult Station TS has additional (non-MD regulated) functionality of remote consultation with a professional health. The data in the Consult Station is HIPAA compliant; therefore this function does not raise new questions in terms of safety/effectiveness in comparison to predicates.

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
Indications for Use	The Consult Station TS is intended to be used by the general public to perform a health check, including the measurement of certain vital signs (temperature, weight and BMI, blood pressure and pulse rate). The lay user autonomously self-performs all the measurements listed above. Using an audio-video conferencing feature incorporated in the Consult Station TS to connect with a healthcare professional remotely, it is possible to perform additional examinations: ENT (Ear, Nose and Throat) and skin examinations, auscultation sounds and blood oxygen level. The lay user and the healthcare professional are able to see and to interact with each other. The Consult Station TS is not intended for diagnostic use. Lay users should consult their personal physician if they have concerns regarding the results of their health check. The Consult Station TS is intended for lay users of fourteen (14) years old or older. The Consult Station TS is not intended for children under the age of fourteen (14). The Consult Station TS can be deployed in indoor public areas, such as: pharmacies, senior living communities, shopping centers, corporations, etc.	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.	Similar general intended use as CSI Model 9K. The addition of new exams in audio-video conferencing feature: insnspection of the external ear canal, body surface examination and auscultation of sounds associated with internal organs and blood oxygen level measurement does not change the general intended use of the Consult Station TS compared with the CSI Model 9K.
Intended Population	General Public (≥ 14 years age). The Consult Station TS is not intended for children under the age of fourteen.	General Public (≥ 14 years age). Children under the age of fourteen must be accompanied by an adult.	The intended population of the Consult Station TS is the same as for the CSI Model 9K.
Hardware design	Serial port using a RS-232 Interface. The touch screen is used as input device for the user. Measurements can be started and stopped using the controls displayed on the touch screen.	Serial port using a RS-232 Interface. The device has a touch screen for user interface. The lay user may select from a menu of items. The lay	The hardware design of the Consult Station TS is similar to the CSI Model 9K.

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
	Once measurements are complete, the results are displayed on a LCD screen. The lay user has to insert the arm in the cuff mechanism before pressing the "Start" button on the touch screen. An "Abort" button would result in the immediate deflation of the cuff and the aborting of the test. This 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) and heart rate. Interactive screens and videos instructions are displayed on a LCD screen. Additionally, the functionality to gain remote access to a professional healthcare is available via a LCD screen. The Consult Station is equipped with a printer.	user has to insert the arm in the cuff mechanism before pressing the "Start" button on the touch screen. LCD touch screen user interface to control and receive blood pressure, pulse rate, weight and temperature readings. A “Start” and “Release” button is provided to control the blood pressure monitoring. The 9K model may also be equipped with a scanner, printer, finger print reader and signature pad. Display /Technology: LCD computer monitor.	
Software design	The Consult Station TS uses a software as an automated system for measuring blood pressure, blood oxygen level, pulse rate, temperature, weight, & height. The system 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 using the Oscillometric method. The software is responsible for starting and stopping measurements. The user is guided by a series of interactive screens and voice instructions. The software controls user credentials (username and password or sex, data of birth for	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 (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	The software design of the Consult Station TS is similar to the CSI Model 9K.

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
	user authentication), voice instructions, presentation movies and the video conference with a remote physician.	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.	
Materials	Resin and glass fiber covered by gelcoat. Not made with natural rubber latex, polyester thread for cuff.	Not available	Materials for CSI Model 9K are not available for comparison.
Components	The physiological parameters measurements available in Unsupervised Mode are:the weight and BMI calculation, the temperature, the blood pressure and the pulse rate. The exams available in Supervised Mode are: ENT examinations (inspection of the external ear canal) using an otoscope, skin surface examinations using a dermatoscope, auscultation of sounds associated with the heart and lungs using a stethoscope and blood oxygen level measurement using a pulse oximeter.	Blood Pressure and Pulse Rate, Weight and Temperature	**Unsupervised Mode:** Both the Consult Station TS and CSI Model 9K measure systolic and diastolic blood pressure, pulse rate and (if optionally equipped for CSI Model 9K) weight and temperature. Lay users may also manually enter or download blood glucose level with both devices. **Supervised Mode:** When using the audio-video conferencing feature, the Consult Station TS integrates additional instruments (pulse oximeter, stethoscope, otoscope and dermatoscope) to perform specific examinations (ENT and skin examinations, auscultation sounds and blood oxygen level) not made available with the predicates. Use of these supplementary functionalities requires guidance of a physician via audio-conferencing to ensure that medical devices are properly placed on the lay user and data is appropriately collected for interpretation by the physician. The selected pulse oximeter (K140785) and stethoscope

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
			(K102893) are FDA cleared for "remote use by a physician using a computer" as they are intended to be used when integrated into the Consult Station TS. No new questions of safety or effectiveness arise from the inclusion of pulse oximeter, stethoscope, otoscope and dermatoscope measuring devices and associated the audio-video conferencing feature.
Dimensions and Weight	6 feet length x 4 feet wide x 7,5 feet tall	Not available	The dimensions for CSI Model 9K Station are not available for comparison.
User Interaction	Interactive screens and voice instructions	Interactive screens	Same (unchanged) as CSI Model 9K.

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
Electromagnetic Compatibility and Electrical Safety	EN 60601-1:2006 and AAMI / ANSI ES60601-1:2005 and AAMI/ANSI ES60601-1:2005 and A1:2012 and A2:2010 IEC 60601-1-11 Edition 1.0 2010-04 Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in homecare environment. Consult Station TS meets requirements of compliance with the standard IEC 60601-1-2 Edition 3: 2007-03; Electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests and, by equivalence with the standard IEC 60601-1-2 Edition 3: 2007 Deviations US and acceptance tests for the home environment and US deviations have been completed according to AAMI/ANSI/IEC 60601-1-2 Edition 4:2014-02 Electrical Safety Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetidisturbances -- Requirements and test.	Electromagnetic compatibility – IEC 60601-1-2 Electrical Safety – IEC 60601-1-1	Same (unchanged) as CSI Model 9K, the Consult Station TS is tested to meet electrical safety and electromagnetic compatibility requirements.
Performance Standards	*Performance testing* – ***Automated sphygmomanometers:*** ANSI AAMI ISO 80601-2-30 :2009& A1 2013 Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive The automated sphygmomanometer has been also subject to clinical tests by their original manufacturer before their integration in the Consult Station TS and meets	***Performance testing*** – according to AAMI/ANSI SP10:2002 Manual, electronic, or automated sphygmomanometers IEC 60601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers No information available on conformance to FDA	ANSI AAMI ISO 80601-2-30_2009 & A1 2013 cancels and replaces the second edition of IEC 60601-2-30, published in 1999. This edition constitutes a major technical revision as well as an alignment with the third edition of IEC 60601-1. Same (unchanged) as CSI Model 9K kiosk.

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
	requirements for Clinical and Performance testing according to EN 1060-4: 2004 Non-invasive sphygmomanometers - Part 4 (Procedures for determining the accuracy of the entire automated non-invasive blood pressure system was completed by the supplier of the blood pressure module) and meets requirement for the standardANSI/AAMI/ISO 81060-2-2013 ***Thermometer:*** - E1965-98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature - ISO 80601-2-56 First Edition 2009-10-01 Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement ***Pulse Oximeter:*** ISO 80601-2-61 First edition 2011-04-01 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter ***Software validation:*** Software validation has been satisfactorily completed according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) for a device of moderate level of concern. IEC 62304: 2006 Medical device software - Lifecycle software process	software guidance	

	Consult Station TS® (subject 510(k))	CSI Model 9K Managed Health System (K101198)	Comparison
Biocompatibility	The blood pressure cuff, the pulse oximeter and the stethoscope are certified to be compliant with ISO 10993. Biocompatibility is established utilizing their original 510k (already FDA cleared). The thermometer and the handle of the of the thermometer, otoscope and dermatoscope are designed by H4D and consists of the PA 2200 (nylon 12) powder manufactured by a sintering process. Biocompatibility tests were performed according to the standard ISO 10993-1.	The blood pressure cuff and thermometer are certified to be compliant with ISO 10993.	Same (unchanged) as CSI Model 9K.
Sterilization	Non-Sterile cleaning and disinfecting instructions are provided.	Non-Sterile	Same (unchanged) as CSI Model 9K.

Table 5-5 compares the similarities and differences between blood pressure monitor module and the predicate Omron Hem-705CP (K903134).

Table 5-5 Comparison of the Blood Pressure Module with Omron Hem-705CP

	Non-invasive blood pressure monitor in the Consult Station®	Omron Hem-705CP automated monitor	Comparison
Device Class	Class II	Class II	Same
FDA code product	DXN	DXN (510k number K903134)	Same
Indications for Use	To measure systolic and diastolic blood pressure. It is not a diagnostic device and only furnishes data so users can consult their personal physician.	To sense the systolic and diastolic blood pressure values.	Same
Intended Use	The Consult Station is intended to be used by the general public.	The Omron blood pressure monitor is intended to be used by the adults	
Intended Population	General Public (≥ 14 years age)	General Public (except infants)	Same
Hardware design	The touch screen user interface is used to control blood pressure. A start, stop and redo buttons start, stop or redo the measurements. The Consult Station is equipped with a printer intended to print the results.	The display panel is used to control blood pressure. The Omron Hem-705CP automated monitor is equipped with a printer.	Same design

	Non-invasive blood pressure monitor in the Consult Station®	Omron Hem-705CP automated monitor	Comparison
Technical Specifications	Measurement range: SYS: 25 to 280 mmHg; DIA: 10 to 220 mmHg Accuracy/calibration: < +/-5 mmHg Measurement method: oscillometric method Operating temperatures: 50°F to 95 °F (10 °C to 35 °C) Storage temperatures : -4°F to 120°F (-20°C to 50°C)	Measurement range : 0 to 299 mmHg Accuracy/calibration: ± 4 mmHg Measurement method: oscillometric method Operating temperatures: 50°F to 104°F (10°C to 40°C) Storage temperatures : -4°F to 140°F (-20°C to 60°C)	Similar characteristics
User Interaction	Interactive screen	Interactive screen	Same
Electromagnetic Compatibility and Electrical Safety	Electromagnetic compatibility – ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02 Electrical Safety EN 60601-1:2006 and AAMI / ANSI ES60601-1:2005	Not available, the 510(k) summary isn't on the FDA database website.	Not available
Performance Standards	Recognized Consensus Standards ANSI AAMI ISO 80601-2-30_2009 & A1 2013 Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers By equivalence, the blood pressure monitor is compliant with the standard AAMI ANSI _ISO 81060-2-2013 Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	Not available, the 510(k) summary isn't on the FDA database website.	Not available
Biocompatibility	The blood pressure cuff is compliant with ISO 10993.	Not available	Not available
Sterilization	Non-Sterile	Non-Sterile	Same

Table 5-6 compares the similarities and differences between IR thermometer module and the predicate Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10) (K).

Table 5-6 Comparison of the Thermometer IR with Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)

	IR thermometer in the Consult Station®	Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)	Comparison
Device Class	Class II	Class II	Same
FDA code product	FLL	FLL (510k number K160816)	Same
Indications for Use	The thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from human skin (temple)	Infrared Thermometer is intended for body temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.	Same
Intended Use	The Consult Station is intended to be used by the general public.	The device can be used by consumers in household environment and doctor in clinic as reference.	Same
Intended Population	General Public (≥ 14 years age)	General Public of all ages	Similar
Hardware design	The thermometer measures the infrared heat generated by the surface of the skin over the temporal artery. The thermometer then converts it into a temperature value shown on LCD. The touch screen user interface is used to control the temperature A start, stop and redo buttons start, stop or redo the measurement. Results in memory can be transmitted to the physician's computer by cable.	The device uses infrared probe to detect the radiated infrared energy emitted by the object, solid, liquid or gas. The intensity of the emitted energy depends on the temperature of the object. The infrared probe can recognize it and transfer to the proper electronic signal. The electronic signal can be processed in the Infrared Thermometer to convert to the temperature reading, which is displayed on the LCD. Therefore, the subject device is able to measure the temperature of a person by the energy the person emits. The body mode is also forehead measurement mode.	Same design
Technical Specifications	Accuracy: ±0.2℃ (±0.4℃) for the range of 32.0°C to 36.0℃ and for 39.0 ℃ t 42.0°C ± 0.1°C from 36,1℃ to 38,9°C ± 32.54°F (± 0.3 °C) from 32 °C - 42 °C (89.6°F- 107.6 °F),	Accuracy: ±0.2℃ (±0.4℃) for the range of 30°to 43°C (86.0°F to 109.4°F) (body mode) Display resolution: 0.1°C/0.1°F	Similar characteristics

	IR thermometer in the Consult Station®	Infrared Thermometer (Model: LX-26E, LX-260TE, PRO LX-261E, LX-360, LX-361T, BW-CX10)	Comparison
User Interaction	Interactive screen	Interactive screen	Same
Electromagnetic Compatibility and Electrical Safety	Electromagnetic compatibility – ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02 Electrical Safety IEC 60601-1-2 Edition 3: 2007-03	IEC 60601-1: 2005+CORR.1 (2006)+CORR.2 (2007), lEC 60601-1-2: 2007, IEC 60601-1-11: 2010, ISO 80601-2-56: 2009	Same
Performance Standards	- E1965-98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature - ISO 80601-2-56 First Edition 2009-10-01 Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	Meet the accuracy requirement specified in ASTM E1965-98 (2009) and ISO 80601-2-56: 2009.	Same
Biocompatibility	The thermometer is compliant with ISO 10993.	Comply with ISO 10993-1:2009, ISO 10993-5: 2009, ISO 10993-10: 2010	Same
Sterilization	Non-Sterile	Non-Sterile	Same

5.8 Conclusion

Unsupervised Mode:

The Consult Station TS has the same intended use (i.e. furnishes medical data so lay users can consult their personal physician) and follows the same principles of operation (i.e. self-performing health check-ups via an automated non-invasive device in the form of a health booth with panels, windows, door and seat) as the predicates.

Both the Consult Station TS and CSI Model 9K measure systolic and diastolic blood pressure, pulse rate and (if optionally equipped for CSI Model 9K) weight and temperature. Lay users may also manually enter or download blood glucose level with both devices.

Supervised Mode:

When using the audio-video conferencing feature, the Consult Station TS integrates additional instruments (pulse oximeter, stethoscope, otoscope and dermatoscope) to perform specific examinations (ENT and skin examinations, auscultation sounds and blood oxygen level) not made available with the predicates. Use of these supplementary functionalities requires guidance of a

physician via audio-conferencing to ensure that medical devices are properly placed on the lay user and data is appropriately collected for interpretation by the physician.

The selected pulse oximeter (K140785) and stethoscope (K102893) are FDA cleared for “remote use by a physician using a computer” as they are intended to be used when integrated into the Consult Station TS.

Under the intended use described above, no new questions of safety or effectiveness arise from the inclusion of pulse oximeter, stethoscope, otoscope and dermatoscope measuring devices and associated the audio-video conferencing feature.

Even though a “Supervised Mode” poses a technical difference compared to the predicate device, as they have similar intended use and as this technical difference does not pose further associated safety risks, H4D believes that Consult Station TS is Substantially Equivalent to the predicate device, CSI Model 9K.