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JUL 26 2012

510(k) Summary
(in accordance with 21 CFR 807.92)

510(k) Number K_____

I. Applicant Information

Applicant:

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Date Prepared: May 4, 2012

II. Device Name and Classification

Proprietary Name:	**icp triagemanager**
Common/Usual Name:	Remote Patient Monitoring System
Classification Name:	Radiofrequency physiological signal transmitter and receiver
Regulation Number:	21 CFR 870.2910
Product Codes:	DRG
Classification:	Class II
Classification Panel:	Cardiovascular Devices

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III. Predicate Device

The **icp triagemanager** device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K103276
Trade Name:	Intel Health Guide Express
Manufacturer:	Intel Corporation
Classification Name:	Radiofrequency physiological signal transmitter and receiver
Common/Usual Name:	Remote Patient Monitoring System
Regulation Number:	21 CFR 870.2910
Product Codes:	DRG
Classification:	Class II

IV. Device Description

The **icp triagemanager** is a web-based, telehealth remote patient monitoring system application used by trained healthcare personnel to access patient's vitals sign data and patient's answers to health related questions.

The **icp triagemanager** allows healthcare professionals to review patient's information and to provide educational or motivational information to the patients. The software also allows medical personnel to predefine upper and lower limits outside of which communication with caregivers is initiated.

The **icp triagemanager** is not intended for direct diagnosis or monitoring of patient's conditions, nor is it intended for providing automated treatment decisions or to be used as substitute for professional healthcare judgment. The system is not intended for real-time monitoring of time-critical data, nor is it intended for patients requiring direct medical supervision or emergency intervention.

The **icp triagemanager** runs on a standard "off-the-shelf" server hosted by the health care facility and allows caregivers to review patient vital signs on the secure website. The patient's physiological data are measured using standard commercially available medical devices designed for home use. These devices communicate via commercially available hub/gateways compatible with the **icp triagemanager** software installed on the host server. The hub/gateways are also medical devices already available for telehealth home use. The hub/gateway systems communicate over a secure internet

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connection to a secure database on the host server running the **icp triagemanager** software.

The main features of the **icp triagemanager** software are:

- Adding/removing patients to/from monitoring list
- Triaging patients based on user defined severity
- Follow up on individual patient measurements and schedules
- Assigning 3rd party monitors to individual patients
- Adding/removing/administering users
- Reviewing and print patient data reports

The main users of the program are trained medical professionals needing telehealth remote monitoring of non-critical patients who do not require emergency intervention. Clinical judgment and experience by a caregiver are always required to interpret the patient information displayed by the **icp triagemanager** software.

V. Intended Use

The Tunstall **icp triagemanager** software application allows the caregiver to review patient information and to motivate and provide educational information to the patient.

The Tunstall **icp triagemanager** is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment. Clinical judgment and experience by a caregiver are required to check and interpret the patient information delivered.

The Tunstall **icp triagemanager** is not intended for real-time monitoring, is not an alarm system and may not be used to receive real-time or time-critical data, is not intended for patients requiring direct medical supervision or emergency intervention, and is not intended for direct diagnosis or monitoring.

VI. Summary of the Technical Characteristics

The **icp triagemanager** is a web application that allows healthcare personnel to log into the system to perform triage of patients based on their vitals data and their answers to predefined questions. Patients' vitals data is received from commercially available remote patient monitoring devices and is stored in the system.

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The **icp triagemanager** application allows remote monitoring of patients with conditions like diabetes, chronic obstructive pulmonary disease, or coronary heart disease, etc.

The principle technical characteristics capabilities of the system are:

- Handle several patients' data individually, where data is collected remotely via external patient monitors;
- Send questionnaires, surveys, etc. from the host-server via a "Generic Patient Monitoring Interface" to external patients;
- Receive patient data and answers from external patient via internet connection via a "Generic Patient Monitoring Interface";
- Support **icp triagemanager** system login for users with role-based access rights and support an administrator role capable of controlling and maintaining the system;
- Restrict access to patients' data;
- Allow the grouping of triage staff into dedicated treatment teams, each with specific clinical specialties;
- Present a graphic overview of patients' data to triage staff, which can be sorted according to customizable users' needs;
- Present patients' data in patient reports that can be displayed online and can be stored as individual files and printed from the system.

The following **Predicate Device Comparison Table** provides a summary of the comparison between the **icp triagemanager** and the predicate device listed in Section III, with respect to intended use, environment of use, limitations of use, principles of operation and technological characteristics. More detailed information regarding the basis for the determination of substantial equivalence can be found at Section 12 of this 510(k) submission.

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Predicate Device Comparison Table

Device Name	icp triagemanager	Intel Health Guide Express (K103276)	Significant Differences
Product Code	DRG	DRG	None
Regulation #	870.2910	870.2910	None
Class	II	II	None
Intended Use	The Tunstall **icp triagemanager** software application allows the caregiver to review patient information and to motivate and provide educational information to the patient.	The Intel Health Guide Express is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys. The Intel Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients.	The **icp triagemanager** and the Intel Health Guide Express have essentially identical Intended Uses, with the difference that **icp triagemanager** does not include a video conferencing feature (please see part in yellow).
Environment of Use	Healthcare providers.	Home users and healthcare providers.	The **icp triagemanager** and the Intel Health Guide Express have essentially identical Environment of Use, with the difference that **icp triagemanager** does not include home users (please see part in yellow).

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Device Name	icp triagemanager	Intel Health Guide Express (K103276)	Significant Differences
Limitations of Use	The Tunstall **icp triagemanager** is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment. Clinical judgment and experience by a caregiver are required to check and interpret the patient information delivered. The Tunstall **icp triagemanager** is not intended for real-time monitoring, is not an alarm system and may not be used to receive real-time or time-critical data, is not intended for patients requiring direct medical supervision or emergency intervention, and is not intended for direct diagnosis or monitoring. To be used upon prescription of a licensed physician or authorized healthcare provider.	The Intel Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The Intel Health Guide Express is contraindicated for patients requiring direct-medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered. To be used upon prescription of a licensed physician or authorized healthcare provider.	The **icp triagemanager** and the Intel Health Guide Express have essentially identical Limitations of Uses.
Principles of Operation	A software application running on a host server that allows caregivers to review (on a secure website) patient vital signs received from commercially available, compatible hub/gateway systems.	A software application that is working as hub/gateway sending data measured by patients to a data server where another software package is used for the review (on a secure website) of patient vital signs.	The **icp triagemanager** and the Intel Health Guide Express have essentially identical Principles of Operation, with the difference that the Intel Health Guide Express includes a hub/gateway system,

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Device Name	icp triagemanager	Intel Health Guide Express (K103276)	Significant Differences
	The system allows user defined upper and lower limits and, when either limit is exceeded, the system email and/or pages the caregiver.	The system allows user defined upper and lower limits and, when either limit is exceeded, the system email and/or pages the caregiver.	whereas the **icp triagemanager** relies on commercially available, compatible hub/gateway systems (please see part in yellow).
Technological Characteristics	**Icp triagemanager** runs on a standard web host server Support for standard internet browsers **Compatible patient data:** • Blood Pressure • Weight • Blood Glucose Level • Oxygen Saturation • FEV/PEV	Intel Health Guide Express Care Management runs on a standard web host server Support for standard internet browsers **Compatible patient data:** • Blood Pressure • Weight • Blood Glucose Level • Oxygen Saturation • FEV/PEV	The **icp triagemanager** and the Intel Health Guide Express Care Management Suite have essentially identical Technological Characteristics

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VII. Summary of Testing

Tunstall Healthcare has conducted extensive verification and validation testing of the **icp triagemanager** system, as a remote patient monitoring system that is capable of providing reliable patient's vitals sign information to healthcare personnel.

All of the different components of the **icp triagemanager** software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate in accordance with its intended use.

The analyses performed included:

- Risk Assessment
- Software verification tests
- Software validation tests

VIII. Conclusions

The **icp triagemanager** conforms to all applicable FDA recognized consensus standards and, based on the comparison of intended use and technological characteristics, is substantially equivalent to the Intel Health Guide Express software manufactured by Intel Corporation (K103276).

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

JUL 26 2012

Tunstall Healthcare
c/o Mr. J.A. (Harry) van Vugt
Responsible Third Party Official
DEKRA Certification B.V.
Utrechtseweg 310, NL-6812 AR Arnhem
The Netherlands

Re: K122095
Trade Name: Tunstall Healthcare icp triagemanager
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Codes: DRG
Dated: July 6, 2012
Received: July 12, 2012

Dear Mr. van Vugt:

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

4. Indication for Use Statement

510(k) Number (if known): K122095

Device Name: **icp triagemanager**

Indications for Use:

The Tunstall **icp triagemanager** software application allows the caregiver to review patient information and to motivate and provide educational information to the patient.

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The Tunstall **icp triagemanager** is not intended for real-time monitoring, is not an alarm system and may not be used to receive real-time or time-critical data, is not intended for patients requiring direct medical supervision or emergency intervention, and is not intended for direct diagnosis or monitoring.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122095