K103276

FEB - 8 2011

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	916 847-7794
Contact Person:	Maureen Glynn
Date Prepared:	01/06/2011

Device Information

Trade Name:	Intel® Health Guide Express
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
1. Intel's Intel® Health Guide PHS6000 **(K080798, K083115 and K101178)**

Device Description

The Intel® Health Guide Express is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. The Intel® Health Guide Express is a software application running on a Commercial Off The Shelf (COTS) Personal Computer (PC). It collects measurements captured on commercially available wireless or tethered medical devices which are designed for home use and connection to a COTS PC. It displays the collected measurement on the PC, and securely stores the collected information locally on a memory device installed in the PC. The Intel® Health Guide Express also stores the information remotely on a host server, where the caregiver can view the measurement via the host server once synchronization between the host server and Intel® Health Guide Express has been completed. The Intel® Health Guide Express can be used to display educational and motivational content from the caregiver and can facilitate communication between the caregiver and patient via health wellness surveys and optional video conferencing.

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. It 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.

The Intel® Health Guide PHS Express system consists of the:

(1) Intel® Health Guide Express software application:

The software application captures, stores, displays and transmits information to a secure database on a host server running the Intel® Health Care Management Suite software via a standard telephone line or internet connection. The Intel® Health Guide Express software runs on a Commercial Off The Shelf (COTS) Personal Computer (PC).

(2) Intel® Health Care Management Suite software application:

The software application runs on a host server and allows caregivers to review patient vital signs on the secure website. The Intel® Health Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

Indications for Use

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 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.

Technological Characteristics

The Intel® Health Guide Express is substantially equivalent to the predicate device Intel® Health Guide PHS 6000 (**K080798, K083115 and K101178**) in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient

device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Table 1: Peripherals Comparison between the predicate device and the **Intel® Health Guide Express**

Physiological Parameter	**Intel® Health Guide PHS6000 (K080798, K083115 and K101178)**	**Intel® Health Guide Express**
Blood Pressure	A&D UA-767PC (K982481)	
Weight	A&D UC-321PBT (exempt)	
	A&D UC-321PL (exempt)	
Blood Glucose Level	Bayer Diagnostics Ascensia Breeze2 (K062347)	
	Bayer Diagnostics Ascensia Contour Blood Glucose Monitoring System (K062058)	
	LifeScan OneTouch Ultra Family of Blood Glucose Monitoring Systems (K043197)	
	LifeScan OneTouch Ultra 2 of Blood Glucose Monitoring Systems (K053529)	
Oxygen Saturation	Nonin 4100 Pulse Oximeter (K043359)	
	N/A	Onyx® II 9560 (K081285)
FEV/PEF	Microlife PF100 (K031024)	

Table 2: Hardware Comparison between the COTS PC meeting minimum specifications and the predicate device[1]

Hardware Parameter	**Intel® Health Guide PHS6000 (K080798, K083115 and K101178)**	**COTS PC**
Operating System	Microsoft Windows XP embedded	Microsoft Windows 7 (32-bit versions)
CPU Core Frequency	1.5 GHz	Minimum: 1.6 GHz (Single Core)
System Memory Size	512MB	Minimum: 1 Gbyte
Pointing Device	HID compliant pointing device	HID compliant pointing device
Available Storage Capacity	40GB	Minimum: 10 Gbytes
LAN Connection	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.
Ports	4 USB Ports	Minimum: 2 USB Ports
SD Card Slot	N/A	Minimum: 1 memory card SDHC compliant with the SD Card Association 2.00 card specification, Class 4 or faster.
Wireless Peripheral Connection	Bluetooth 2.0 Interface	Bluetooth 2.0 Interface
Display	600 x 800 18 bit color	Minimum: 1024 x 600 24 bit color
Speakers	1 Mono	Minimum: 1 (mono)
Microphone	1 Mono	Minimum: 1 (mono)

[1]Differences are to accommodate the Microsoft Windows 7 operating system

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Table 3: Main difference between the COTS PC meeting minimum specifications and the predicate device

Parameter	Intel® Health Guide PHS6000 (K080798, K083115 and K101178)	COTS PC
Safety Standard	ES60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic and essential performance	UL 60950-1:2007 Information Technology Equipment – Safety – Part 1: General Requirements
Patient Leakage Current – From Patient connection to earth[1]	100µA	3.5mA

[1]This is not meant to be an exhaustive list of differences between ES60601-1 and UL 60950-1 but highlights the differences covered in the risk analysis for a COTS PC used with the Intel® Health Guide Express.

Safety and Efficacy

The Intel® Health Guide Express does not rely on an assessment of clinical performance data. The device will conform to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

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

Intel Corporation
c/o Ms. Maureen Glynn
1900 Prairie City Rd.
MS FM7-197
Folsom, CA 95630

FEB - 8 2011

Re: K103276
Trade Name: Intel Health Guide Express
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Glynn:

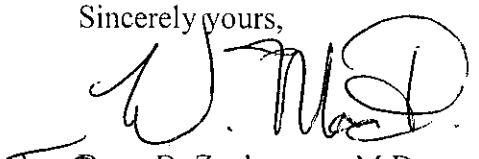
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

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510(k) Notification Submission – Abbreviated
Intel Corporation, Inc.
Intel® Health Guide Express

Indications for Use:

510(k) Number: _____

Device Name: Intel® Health Guide Express

Indications for Use:

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

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