SEP 1 0 2009

Alcatel·Lucent

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K092635

I. Applicant Information

Applicant:

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Markham, Ontario
Canada L3R 4G5

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President
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Application Correspondent:

SALVEO
101-2550 Sandra Schmirler Way
Regina, SK S4P 3Y2
Canada

Contact Person: Ms. Pat Tulloch,
Chief Operating Officer
Tel: (306) 337-0506
Fax: (306) 337-0512
e-mail: pat.tulloch@salveo.ca

Date Prepared: July 3, 2009

II. Device Name and Classification

Proprietary Name:	Alcatel-Lucent TeleHealth Manager
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Telemedicine System
Regulation Number:	870.2910
Product Codes:	DRG
Classification:	Class II
Classification Panel:	Cardiovascular Devices

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III. Predicate Devices

The Alcatel-Lucent TeleHealth Manager device is substantially equivalent to the following two FDA cleared predicate devices:

510(k) Number:	**K040966**
Trade Name:	Carematix Wellness System
Manufacturer:	Carematix, Inc.
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Telemedicine System
Regulation Number:	870.2910
Product Codes:	DRG
Classification:	Class II
SE with respect to:	Indications for use, performance and technological characteristics

510(k) Number:	**K072698**
Trade Name:	Confidant 2.5
Manufacturer:	Confidant International, LLC
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Telemedicine System
Regulation Number:	870.2910
Product Codes:	DRG
Classification:	Class II
SE with respect to:	Communication method with the hosting server

IV. Device Description

Alcatel-Lucent TeleHealth Manager is a software system that collects patient physiological data such as blood pressure and blood sugar levels, via Bluetooth technology combined with cellular or plain old telephone system (POTS) home access point, for transmission to a secure central storage server which can be accessed by health care professionals for analysis and intervention. This data is also available to the patient for viewing purposes and as an aid in the self management of their specific health condition.

As Alcatel-Lucent TeleHealth Manager main function is to relay a reading to the appropriate users without alteration or post processing of the measurement, it is the responsibility of the patient-user to verify that the reading has been correctly executed.

With respect to patient data privacy, patient data is encrypted by the Alcatel-Lucent TeleHealth Manager system in such a way that it can be securely accessed only by the authorized users.

V. Intended Use

Alcatel-Lucent TeleHealth Manager is a Remote Patient Monitoring solution intended to provide monitoring services of patient vital signs and other physiological data by remote data transmission from a patient to the practitioner.

The system can be used by patients during their daily lives and allows the collection, recording and transmission of physiological information such as blood glucose levels, using a glucometer, and non-invasive blood pressure measurements.

The transmission of data to a secure server hosting platform is carried out over existing telecommunications infrastructure via common telephone lines and mobile networks. The data is collected in a secure server hosting platform, which stores the information and allows its remote access by the patient and/or health care professional.

Alcatel-Lucent TeleHealth Manager is intended as an aid for the continuous monitoring of physiological processes and is not intended as a replacement of the medical oversight of a trained healthcare professional.

VI. Summary of the Technical Characteristics

The Alcatel-Lucent TeleHealth Manager system is comprised of a software component (downloaded and installed by the user in their mobile phone), a central server component (for secure data storage), a web communication protocol component (for making data available on line), and a SMTP getaway and Interactive Voice Response system components (used for user and/or health care provider notification).

Collection, transmission, and storage of physiological and lifestyle data originating from patients is part of this automated telemonitoring system. The system incorporates the necessary communication protocols to enable the patient to use home medical monitoring devices such as a blood pressure monitor or a glucometer. Readings are taken in the same fashion as any patient currently using these devices would do. Data readings remain in the original medical monitoring devices as per manufacturer's specifications.

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VII. Testing

Alcatel-Lucent has conducted extensive validation testing of the Alcatel-Lucent TeleHealth Manager system, as a telemonitoring system that is capable of providing reliable remote patient monitoring functionalities. Testing was carried out to verify the product requirements and functional specifications, to verify that the physiologic data received by the patient measuring devices is stored properly and to verify that the data is transmitted to the healthcare practitioner in a manner that maintains the security and integrity of the information. All of the different components of Alcatel-Lucent TeleHealth Manager have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

VIII. Safety & Effectiveness Conclusions

Based on the comparison of intended use and technological characteristics, the Alcatel-Lucent TeleHealth Manager system is substantially equivalent to the Carematix Wellness System manufactured by Carematix, Inc. (K040966), with respect to indications for use, performance and technological characteristics, and to the Confidant 2.5 (K072698) manufactured by Confidant International, LLC, with respect to the communication method with the hosting server.

The Alcatel-Lucent TeleHealth Manager device raises no new safety or effectiveness issues.

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

SEP 10 2009

Alcatel-Lucent Canada, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K092635
Trade/Device Name: Alcatel-Lucent TeleHealth Manager
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG, DXN, NBW
Dated: August 26, 2009
Received: August 27, 2009

Dear Mr. Job:

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.

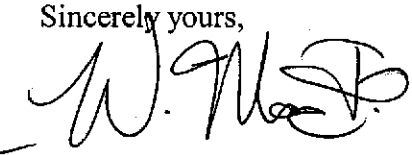
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

4. Indication for Use Statement

510(k) Number (if known): K092635

Device Name: **Alcatel-Lucent TeleHealth Manager**

Indications for Use:

Alcatel-Lucent TeleHealth Manager is a Remote Patient Monitoring solution intended to provide monitoring services of patient vital signs and other physiological data by remote data transmission from a patient to the practitioner.

The system can be used by patients during their daily lives and allows the collection, recording and transmission of physiological information such as blood glucose levels, using a glucometer, and non-invasive blood pressure measurements.

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Alcatel-Lucent TeleHealth Manager is intended as an aid for the continuous monitoring of physiological processes and is not intended as a replacement of the medical oversight of a trained healthcare professional.

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_____