# PREMARKET NOTIFICATION 510(k) SUMMARY
## As required by 21 CFR §807.92(c)

JUL 30 2013

### Submitter

| | |
|---|---|
| 510(k) Owner: | MedApps, Inc., DBA Alere Connect |
| Owner / Operator: | 10027842 |
| Registration: | 3005916763 |
| Address: | 8767 E. Via De Ventura, Suite 300, Scottsdale, AZ 85258 |
| Telephone: | 480-305-6323 |
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| Contact Person: | Kent Dicks |
| Contact Person Title: | CEO |
| Date Prepared: | December 12, 2012 |

### Device Information

| | |
|---|---|
| Trade Name: | MedApps 2.0 - Remote Patient Monitoring System |
| Common Name: | Remote Patient Monitoring System |
| Classification Status: | Class II per regulations 870.2910 |
| Classification Name: | Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG) |

### A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate devices are:

| | |
|---|---|
| K080798 | Intel Health Guide PHS6000 |
| K040966 | Carematix Modified System |
| K083862 | MedApps 2.0 - Remote Patient Monitoring System |

### B. INDICATIONS FOR USE

The MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System consists of 1) a cellular communication hub (MedApps' HealthPAL or MobileLink) an over-the-counter device that resides with the end-user (patient), which connects to commercially available FDA cleared accessory devices, specifically glucose meters, scales, blood pressure monitors, pulse oximeters, and PT/INR monitors and 2) web-based health data management application (MedApps' HealthCOM), that provides access to collected data stored on a secure host server system.

MedApps Inc., DBA Alere Connect Remote Patient Monitoring devices receive and store measurements collected from the described accessory devices, either wirelessly using short-range radio protocols (e.g. Bluetooth, Zigbee, WiFi, Bluetooth Low Energy (BLE), Fitlinxx Radios) or tethered via cable (e.g. USB, serial, etc). Regardless of connectivity mode, the MedApps / Alere Connect monitoring devices do not alter the indications for use of the described peripheral accessory health devices.

MedApps/Alere Connect devices indicate successful or failed data reception and transmission with visual and audio feedback using a combination of any of the following: OLED Display, LED Lights, verbal messages, and/or audio tones/chimes. MedApps/Alere Connect devices store collected data and forward/transmit to server for access in HealthCOM via commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals, clinicians and other authorized personnel can review the transmitted information within the MedApps HealthCOM system, where they can review collected readings, establish parameters to indicate readings exceptions to set thresholds, or trigger Interactive Voice Response (IVR) messages to the patient remotely to issue information such as reminders (e.g. "We haven't received readings from you today, please take and send your readings") or possibly educational information for conditions such as diabetes, hypertension, CHF, etc. Additionally, HealthCOM can port collected data to the healthcare providers' clinical back-end system(s) of choice.

The MedApps 2.0 (Alere Connect) - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, nor is it intended to provide real-time / time-critical data. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

## C. MedApps 2.0 SYSTEM DESCRITPION

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) HealthPAL hardware:

The physical component of the HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless module, LED lights to indicate activity, timer button to assist patients with their reading schedule (i.e. remind them to take their reading in X minutes), last reading button, volume up and down buttons. The HealthPAL Model 105 contains a GSM cellular module while the HealthPAL Model 106 contains a CDMA cellular module.

(2) HealthHUB hardware / software:

The HealthHUB hardware is an extension of the HealthPAL functionality. HealthHUB acts as a "docking" station for the HealthPAL in order to act as a conduit for the AC power adaptor connecting the electrical wall outlet to the HealthPAL providing power and battery charging capability. The Hubs also provide additional connections to off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, via smart cables (per validated in HealthPAL software). The HealthHUB model MA200 allows for multiple wired connections for accessory devices. HealthHUB Model 205 is specific for the HealthPAL MA105, and the HealthHUB 206 is specific for the HealthPAL MA 106 with both Hubs having one wired connector.

(3) HealthPAL firmware / software:

The firmware captures data from commercially available health monitors, and stores and transmits the information to the HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthPAL to receive information via wire or via embedded wireless module from accessory medical devices that are compatibly wireless enabled, which have been paired to the MedApps HealthPAL.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthPAL remotely.
- HealthPAL has audio capability to deliver verbal announcement of readings and acknowledgment of data transmission from all connected accessory medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.
- Timer capability, activated by the user to provide assistance with adhering to a reading schedule (reminders to take readings within a set timeframe).
- OLED screen displays information regarding the HealthPAL's status including battery level, volume level, data transmission status, transmission pending indicator, activity icons / messages and other information to provide ease of use and promote patient adherence; as well as information received from accessory medical devices, such as the type of device, measurement, date and time of the last reading collected.
- Battery charging, isolation circuits, and interfaces to individual accessory medical devices / protocols via the smart cable.

(4) MobileLink (formally HealthAIR) hardware / software:

AC020 MobileLink is a modified MA105 HealthPAL device. The physical component of the MobileLink is an electronic device contained in a plastic enclosure with built-in M2M cellular chip, speaker, standard USB cable and USB Smart Cable connection, OLED screen to review the reading, and LED lights to indicate activity regarding the receiving and transmitting of collected data.

Like the HealthPAL, MobileLink's firmware / software captures, data from commercially available retail health monitors, and stores and transmits information to the HealthCOM server, via the embedded communication chip / platform.

The firmware allows MobileLink to receive information via wire, either standard USB or with a customized USB Smart Cable, from accessory medical devices.

The firmware has many additional functions including:

- Download of user profiles from the server to configure MobileLink remotely.
- MobileLink's Audio feature uses audio tones to indicate acknowledgment of collected readings from all connected accessory

medical devices as well as reading transmission via the cellular network.

- MobileLink's visual user interface utilizes an OLED display to display collected readings from attached accessory medical devices as well as reading transmission acknowledgements. MobileLink's visual interface also contains a LED light to show power and provide reading request indication capability.

(6) MedApps HealthCOM software application:

The HealthCOM software application allows caregivers access to review patient data collected from accessory medical devices using MedApps hardware on the secure HealthCOM website. HealthCOM software allows professional caregivers to set patient readings.

HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record or Medical Record (EHR or EMR).

(7T) MedApps IVR software application:

The IVR (Interactive Voice Response) software application provides the ability to contact the patient remotely, by phone (designated in the user profile), and executes an pre-approved ("canned") scripts to deliver pre-approved ("canned") reminder messages ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings"), educational content and gather survey information.

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on clinically defined parameters / thresholds established in HealthCOM by the professional care provider.

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

## D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

| **Feature** | **Intel Health Guide PHS6000**<br>**K080798** | **Carematix Modified System**<br>**K040966** | **MedApps Submission**<br>**K083862** | **MedApps 2.0 Submission**<br>**K124000** |
|---|---|---|---|---|
| **Indications of Use** | Enables healthcare providers to monitor and manage chronic conditions of patients remotely | Physiological monitoring system that collects, accumulates and transmits patient vital isgnes and other physiological data from a patient who may be remote form the | The MedApps 2.0 - Remote Patient Monitoring System consists of a<br>patient device, MedApps HealthPAL, ..... | Same as MedApps with the exception of updates to include MobileLink device and PT/INR monitors |
| **Intended Use** | Telemedicine System | Telemedicine System | Telemedicine System | Same as PHS6000, Carematix, and MedApps |
| **Intended Users** | Home users and Healthcare providers | Same | Same | Same |
| **Site of Use** | Home & Clinic | Same | Same<br>Home (HealthPAL) Clinic (HealthCOM) | Same<br>Home (HealthPAL/ MobileLink); Clinic (HealthCOM) |
| **Data Collection Software** | Intel Care Management Suite Software | Proprietary Software | MedApps Proprietary Software | MedApps Proprietary Software |
| **Data Collection Software Functionality** | Transmit data from Sensor devices to Central | Same | Same | Same |
| **Communication method of hub with Central Server** | Via DSL or Phone Line Connection | Via modem over telephone line | Via Embedded Cellular Technology | Via Embedded Cellular Technology |
| **Types of sensors which can be interfaced (wired or wirelessly) to receiver hub** | Medical Devices designed for Home:<br>Glucose<br>Scale<br>Blood Pressure<br>Pulse Ox<br>Peak Flow | Medical Devices designed for Home use:<br>Glucose, Scale<br>Blood Pressure<br>Pulse Ox,<br>FEX/PEF,PT/INR<br>Temperature | Medical Devices designed for Home use:<br>Glucose,Scale<br>Blood Pressure<br>Pulse Ox | Same as MedApps (Glucose, Scale, BP, Pulse Ox with PT/INR)<br><br>Same as CareMatix |
| **Maximum number and type of measurement devices that can be connected to the devices** | Determined by vital sign devices that are designed for Home use, and have a data port. (Wireless or Wired) | Same | Same | Same |

**MedApps, Inc., DBA Alere Connect**
**510(k) SUMMARY**

| Feature | Intel Health Guide PHS6000<br>K080798 | Carematix Modified System<br>K040966 | MedApps 2.0 Submission<br>K083862 | MedApps 2.0 Submission<br>K124000 |
|---|---|---|---|---|
| **Maximum data throughput under worst case conditions** | Multiple readings are stored on the medical devices and act as a backup if data needs to be re-sent to the server | Same | Same | Same |
| **Time Delay in the processing of data collected and transmitted** | Readings stored in the medical devices can be sent up to the server when the connection is restored. | Same | Same | Same |
| **Implementation method of collecting data from sensors** | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Modify OTS sensors with previous 510k approval by adding communications | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Short range radio system using Wired (tethered) |
| **Sensor Software** | Sensor Software unchanged | Same | Same | Same |
| **Connectivity** | Short range radio system using Bluetooth and Wired (tethered) cables. | Wired or wireless to hub | Short range radio system using Bluetooth and Wired (tethered) cables. | Short range radio system using Wired (tethered) |
| **Communication method of hub with devices** | Short range radio system using Bluetooth and Wired (tethered) cables. | Wireless RF protocol | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Short range radio system using Wired (tethered) |
| **Communications Protocol** | Bluetooth V2.0 and Wired (Tethered) | Proprietary | Wireless (Bluetooth) V2.0 and Wired (Tethered) | Wired (Tethered) |
| **Communication Frequency** | Bluetooth : 2.402 to 2.480 GHz | 915 MHz FCC assigned channel | Bluetooth : 2.402 to 2.480 GHz (HealthPAL) GSM: 850 / 900 / 1800 / 1950 Mhz | (HealthPAL or MobileLink) GSM: 850 / 900 / 1800 / 1950 Mhz |
| **Power Source** | Wall power plug (120 VAC/50-60) | Wall power plug (120 VAC/50-60) and Batteries in Device | Wall power plug (120 VAC/50-60) or Rechargeable Battery (HealthPAL) | Wall power plug (120 VAC/50-60) or Rechargeable Battery (HealthPAL or MobileLink) |
| **Display** | On devices and hub, and monitors connected to central server | Same | Same | Same |

| | | | | |
|---|---|---|---|---|
| **Communication with Patients** | On screen display | Same | On screen display of Readings, Voice Output and Interactive Voice | On screen display with audio tones instead of voice. |
| **Use of Thresholds / Algorithms for determining how Thresholds are set and changed** | Thresholds are set by Healthcare professionals in Server Software | Same | Same | Same |
| **Information presented to the user, if it is different from that presented by the measurement devices** | On screen display | Same | Audio/visual reading feedback on screen and by speaker; and Interactive Voice Response (IVR) System for patient contact | Visual reading feedback on screen and audio tone by speaker; and Interactive Voice Response (IVR) System for patient contact |
| **Messages and Instructions that can be sent to the User.** | On screen display | Same | On screen display of Readings, Voice Output and Interactive Voice Response (IVR) | On screen display of Readings, Voice Output and Interactive Voice Response (IVR) |

**MedApps, Inc., DBA Alere Connect**
**510(k) SUMMARY**

Below is a Technological Characteristics Summary Comparison between the MA105 HealthPAL and the AC020 MobileLink medical devices:

| Feature | MA105 HealthPAL | AC020 MobileLink |
|---|---|---|
| **Indications of Use** | Enables healthcare providers to monitor and manage biometirc patient data collected remotely | Same |
| **Intended Use** | Telemedicine System | Same |
| **Intended Users** | Home users and patients outside of the clinical setting, as well as Healthcare providers for HealthCOM | Same |
| **Site of Use** | Remote setting (e.g. Home / Work), Clinic | Same |
| **Data Collection Software & firmware** | MedApps Proprietary Software | Same |
| **Data Collection Software Functionality** | Transmit data from Sensor devices to Central Database | Same |
| **Communication method of device hub with Central Server** | Via Embedded Cellular Technology (GSM or CDMA) | Same |
| **Types of sensors which can be interfaced (wired or wirelessly) to receiver hub** | Medical Devices designed for Home use:<br>Glucose, Scale, Blood Pressure Pulse Ox (adding PT/INR with this submission) | Same |
| **Transmission** | Transmits information to the MedApps secure host server called "HealthCOM" | Same |
| **Implementation method of collecting data from sensors and general Connectivity** | Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables). | MobileLink uses wired / tethered connection (USB, Smart Cables) |
| **Communication method of hub with devices** | Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables). | MobileLink uses wired / tethered connection (USB, Smart Cables) |
| **Communication Frequency** | Bluetooth : 2.402 to 2.480 GHz<br>GSM: 850 / 900 / 1800 / 1950 Mhz | No Bluetooth capability<br>GSM: 850 / 900 / 1800 / 1950 Mhz |
| **Power Source** | AC adaptor Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device | AC Adaptor that is 60601-1 3rd Edition compatible with Lithium battery only used for soft shut down functionality and not powering device. |
| **Device Communication with Patients** | On screen display and audio voice feedback | On screen display with audio tones instead of voice. |
| **Certification Testing** | Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, FCC Bluetooth, (PTCRB), CTIA (battery), ETSI | Safety 60601-1 3rd Edition, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, (PTCRB- in process), ETSI *(See Declaration of Conformity)* |

**Data Collection:**
The 2 predicate devices and the MedApps solution connect to medical devices (designed for home use) by either wired (cable) connection or wireless (HealthPAL- Bluetooth). The data is collected from the devices and sent to a secure central server using various communication methods.

**Telecommunication Platform to Central Server:**
Intel Health uses DSL connectivity (wired point of care), Carematrix uses modem off telephone line; MedApps uses embedded Machine to Machine (M2M) module to transmit data via cellular connectivity.

**Patient Feedback Technology:**
The 2 predicate devices and the MedApps solution allow data and messages to be displayed on a screen (for the HealthPAL) for the patient to read and acknowledge. MobileLink also uses audio and visual acknowledgement / feedback. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to communicate with the patient and ask questions, gather survey information, or issue reminders.

**Backend Data Storage:**
All systems (both 2 predicate devices and the MedApps solution), provide a backend system that allows data to be stored, and healthcare professionals to access and monitor collected patient data.

**Types of sensors which can be interfaced (wired or wirelessly) to receiver hub:**
CareMatix Modified System and the proposed MedApps 2.0 System both include PT/INR monitor as an FDA cleared accessory device to the receiver hub. The CareMatix uses wireless connectivity to the hub whereas the MedApss 2.0 systems uses both wired and wireless connectivity to the hub. CareMatix System 510k (K040966) clearance summary letter includes the predicate Avid Care (K011779 and K010029) telemedicine system that connects to PT/INR monitor as an accessory device.

## E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

**Non-Clinical Testing**
The submitted 2.0 System has undergone MedApps' design control verification and validation testing. MedApps 2.0 validation testing include testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP.

MedApps 2.0 System verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis, certification standards, and Verification plans. MedApps Product Verification and Release Plan execution on both HealthPAL and MobileLink ensure both medical devices work with each type of user accessory medical device (glucose, blood pressure monitor, scale, pulse oximeter and PT/INR) as part of the MedApps 2.0 System including integration to HealthCOM backend software application. The output of these design control verification analysis documents **MedApps 2.0 - Remote Patient Monitoring System** shall meet its requirements and design specifications as intended.

Lastly, all relevant certification testing such as EMC (60601-1-2) and Safety (60601-1) are described in MedApps' Declaration of Conformity.

## F. SUBSTANTIAL EQUIVALENT

The MedApps 2.0 Remote Patient Monitoring System is substantially equivalent to the predicate devices 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 integrated to the patient medical device, implementation methods of collecting data from sensors, sensor software, connectivity, communication protocol, power source and general display method.

The MobileLink (formally called HealthAIR communication hub device, described in 510(k) K112559) is substantially equivalent to the HealthPAL (described in 510(k) K083862) as both devices, as part of the MedApps 2.0 System, connect to commercially available Glucose Meters, Scales, Blood Pressure Monitors, Pulse Oximeters, and PT/INR; data is collected, stored and transmitted using off-the-shelf FCC approved wireless / cellular connectivity. Both provide audio and visual feedback / acknowledgement that readings have been collected and transmitted to MedApps' secure host server called "HealthCOM".

## G. SAFETY AND EFFICACY

The MedApps 2.0 Remote Patient Monitoring System does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device does not introduce any new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

MedApps, Inc. DBA Alere Connect
C/O Mr. Kent E. Dicks
CEO
8767 E. Via De Ventura, Suite 300
Scottsdale, AZ 85258

Re: K124000
Trade/Device Name: MedApps 2.0 Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II
Product Code: DRG
Dated: January 18, 2013
Received: July 3, 2013

Dear Mr. Kent E. Dicks:

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 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. 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,

Owen P. Faris -S

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

Enclosure

**MedApps, Inc., DBA Alere Connect**
**STATEMENT OF INDICATIONS FOR USE**

510(k) Number: K124000_____

Preparation Date: December 12, 2012

Device Name: **MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System consists of 1) a **cellular communication hub** (MedApps' HealthPAL or MobileLink) an over-the-counter device that resides with the end-user (patient), which connects to commercially available FDA cleared accessory devices, specifically glucose meters, scales, blood pressure monitors, pulse oximeters, and PT/INR monitors and 2) web-based health data management application (MedApps' HealthCOM), that provides access to collected data stored on a secure host server system.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____X_____
(Per 21 CFR 801.109)

Digitally signed by
Owen P. Faris -S
Date: 2013.07.30
09:07:15 -04'00'