DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

MedApps, Inc.
c/o Mr. Kent Dicks
President & CEO
7975 North Hayden Road, Suite A-200
Scottsdale, AZ 85258

Re: K083862
Trade/Device Name: MedApps 2.0 Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 31, 2009
Received: April 1, 2009

Dear Mr. 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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

MedApps, Inc.
STATEMENT OF INDICATIONS FOR USE

EXHIBIT 01

510(k) Number: K083862

Preparation Date: December 23, 2008

Device Name: **MedApps 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or 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").

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083862