



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

DEC - 2 2011

MedApps, Inc.
c/o Mr. Kent Dicks
Founder / CEO
7975 North Hayden Road, Suite A-203
Scottsdale, AZ 85258

Re: K112559
Trade/Device Name: Modification to 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 (two)
Product Code: DRG
Dated: October 25, 2011
Received: November 3, 2011

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. 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.

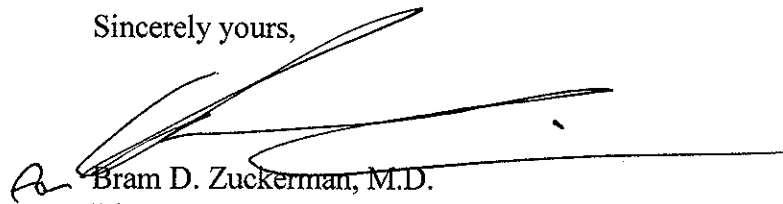
Page 2 – Mr. Kent Dicks

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" (21 CFR 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

510(k) Number: K112559

Preparation Date: August 31, 2011

Device Name: **Modification to 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, a mobile over-the-counter wireless communication hub, or MedApps HealthAIR, a portable over-the-counter wireless communication hub, which connects to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters and HealthCOM, MedApps' secure host server system.

MedApps Remote Patient Monitoring devices receive and store measurements collected from the described monitors, either wirelessly (HealthPAL) or tethered (HealthPAL or HealthAIR). MedApps devices do not alter the indicated use of the peripheral monitors that they integrate with. MedApps devices indicate successful or failed reception and transmission of data with visual and audio cues (HealthPAL via OLED display screen, verbal message and audio tones; HealthAIR via LED lights and audio tones). MedApps devices store collected data and transmit to HealthCOM using commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular 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)


**(Division Sign-Off)
Division of Cardiovascular Devices**

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