Mobile Medical Devices & Apps
Submittal of the MMDA 510(k)

General Information

Blockchain-Medical's objective is to create a product to help smooth the process of at-home patient care. With the rise of health applications and the digital information age, more and more people are turning to technology to complete everyday life tasks. Additionally, with improvements in the medical field, there is a growing focus on monitoring and prevention of patients in the hopes of preventing more serious health problems down the line. Noticing these trends, Blockchain-Medical has designed a product to help the everyday, at-home patient be able to monitor their health from the comfort of their own home and communicate that information to their trusted clinicians through a safe and easy manner. Classic equipment for taking vital signs is expensive and bulky and can be burden to have in the home. Blockchain-Medical's remote patient monitoring device, called Blue Health, is small, portable, and easy to use. The idea is that patients can use this device as often as necessary to communicate with their clinicians and monitor their health by having all of the necessary information in one convenient place. The patient can share their vital signs with their clinician, set reminders, and message clinicians all from one centralized application that syncs with the hardware used to take the vital signs. We hope this product will be a more efficient, easy to use, and affordable way to change the way at-home patients monitor their health.

Statement of Indications for Use

Blockchain-Medical's remote patient monitoring system is intended to be used as a self monitoring device for patients and as a tool for clinicians to interact and engage with their patients remotely and receive their data without the need for hospital visits from the patient. It is a non-invasive patient monitoring system designed to help facilitate out-patient care but not replace medical care available at a hospital or clinic and it is not intended for diagnosis. Both patients and clinicians are intended to use the application, while patients are intended for both the application and device.

The patient's vital signals are transmitted securely from the device to the application running on their mobile phone (running iOS). From there, patients can view their current signals, as well as historical data and trends from previous recordings. Patients can also set notes on the schedule page of the application to keep track of medications and appointments, and can communicate directly with the clinician's office. Clinicians may also use the application to keep track of their registered patients remotely, viewing their vitals with given permission. Clinicians also have the

ability to set reminders on the patient's schedule and message them directly and securely regarding health related matters.

510(k) Summary

Applicant/Submitter:

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BlockchainMedical, LLC.
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Date Prepared:

May 1st, 2018

Trade name:

Blue Health

Common name:

Remote Patient Monitoring Device and Application.

Classification:

Class II
21 CFR 870.1025, Product Code: MHX

- Monitor, physiological, patient (with arrhythmia detection or alarm).

Predicate Device(s):

MedApps 2.0 - Remote Patient Monitoring System, 510(k) #k083862
VitalConnect Platform, 510(k) #: k141167
S Health, 510(k) # k132148

Device Description

The Blockchain-Medical remote patient monitoring platform is a combination of application software for mobile device (running on iOS) and a hardware device in the form of a Raspberry Pi used to transmit patient signals to the application on the mobile device. This mobile application displays various vitals (including ECG, heart rate, oxygen levels, etc.) and provides a central hub for patients to log reminders for taking medication, remembering medical appointments, and other health related matters. In addition, the application allows direct contact messaging between patients and clinician offices.

Indication for Use:

Blockchain-Medical consists of both an iOS application and physical device to monitor various vital signals. Patient signals are sent from the physical device to the application securely through encrypted communication and are displayed to the user in the form of real-time waveforms and general averages. It is intended to be used as a self monitoring device for patients and as a tool for clinicians to interact and engage with their patients remotely and receive their data without the need for hospital visits from the patient.

Blockchain-Medical is intended for patient and clinician use to better facilitate data driven communication in out-patient care. It is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real-time data for non ECG signals.

Performance Data (Non-Clinical):

The submitted device has undergone significant verification and validation testing in both checking the robustness of the software as well as the hardware of the physical device used in transmitting patient signals. All recovery mechanisms for reviving lost connections between the device and application have been tested and proven successful in ensuring quality connection and transmission of signals. In addition, authentication methods have proved to be robust in preventing unauthorized access to the application and its secured patient data.

Substantial Equivalence:

The Blockchain-Medical application and device is substantially equivalent to the predicate devices and applications in terms of data collection software functionality, types of sensors which can be interfaced to the patient/clinician application, implementation method of collecting data from sensors, connectivity, communication protocol, and general user usage of the application and device.

Conclusion

The results of testing Blockchain-Medical's remote patient monitoring application and device demonstrate that it is safe and effective for its intended use, including use in the home environment.

Based on the intended use and product performance results, Blockchain-Medical is substantially equivalent for usage to the current marketed predicate device MedApps 2.0 and others in that domain.

Truthful and Accurate Statement

I certify that, in my capacity as CTO of Blockchain-Medical, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Proposed Labeling

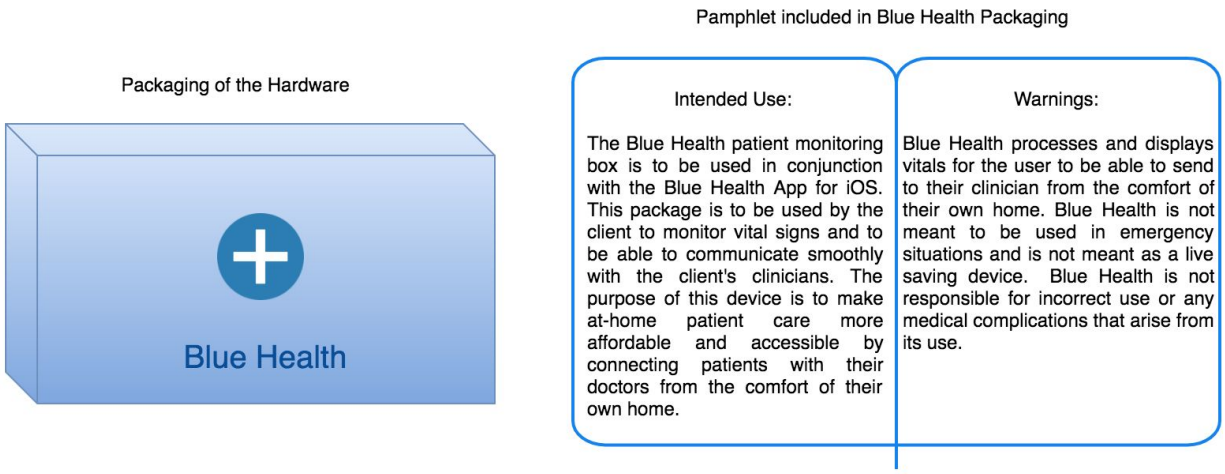

Figure 1: Labeling

The labeling and packing of this product includes a small box that contains the hardware and a pamphlet with instructions of intended use and warnings to the user. We believe these labels and packaging clearly state the intended use and all appropriate warnings and disclaimers. We do not believe our product is dangerous to use or that any persons should be prohibited to use this device as it is non-intrusive.

Specifications

The Blue Health medical device is a two-part package. It consists of hardware that is used to take in the patient's vital signs and sends this data to a software application that the user can download onto their iOS device. The hardware comes packaged in a small box. This box needs to be powered off of 5V by plugging a USB cord into a charger or into one's computer. The hardware runs off of a Raspberry Pi and an A/D converter. The data is converted to digital to be processed by the Blue Health app. Once the device is powered on, the user can connect up to the device to take vitals such as temperature, heart rate, etc. This data uses wifi connection set up by the user to send the data to the app. The app connects to the cloud via Google's database Firestore and saves this data to be used as historical data in order for the user to see a trend in their vital signs. The user can also connect with their clinicians by adding them on their app and giving them permission to view their information and to send messages back and forth. The user can revoke these permissions at any time. Additionally, the user or their clinicians can set reminders about taking medications or appointments in the form of a calendar.

The intended use is that the patient will use this device to take rudimentary vital signs and be able to monitor this and communicate this data to their clinician. This is not intended to be a life saving device, but rather a device that will make at-home patient care easier and more organized for both the patient and the clinician.

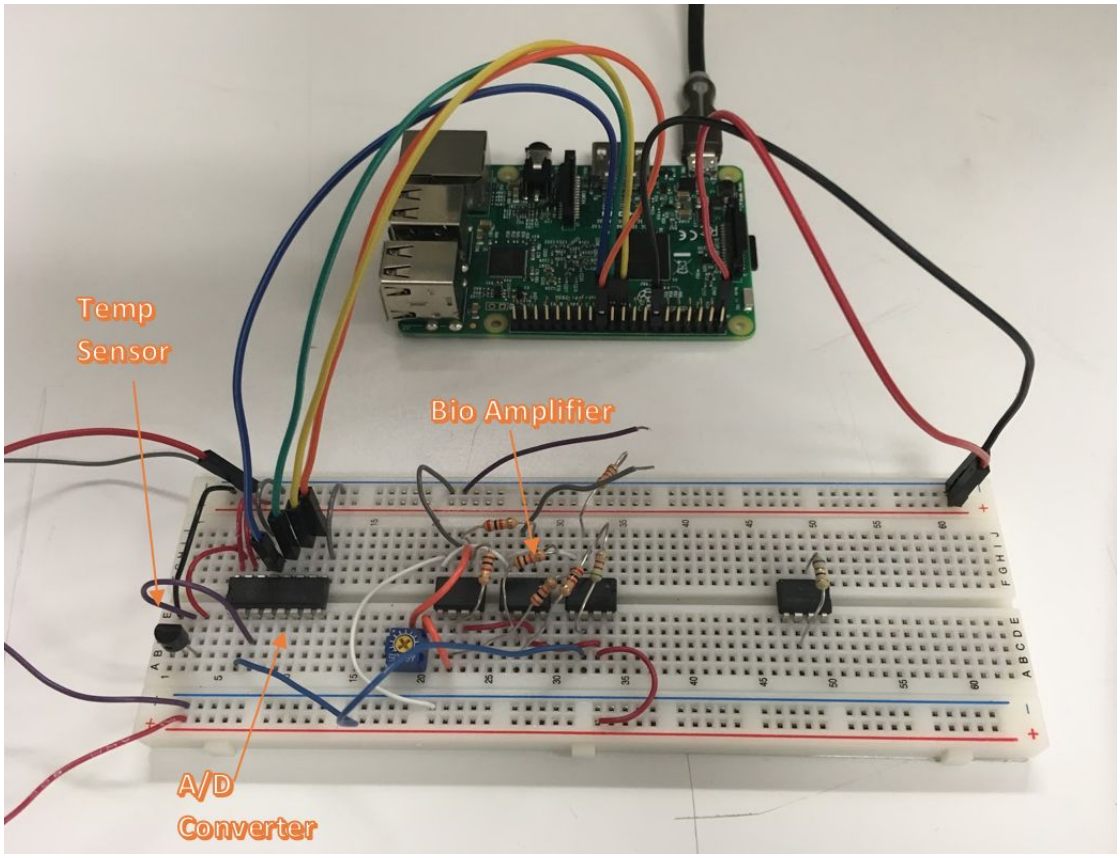

Figure 2: Hardware Device

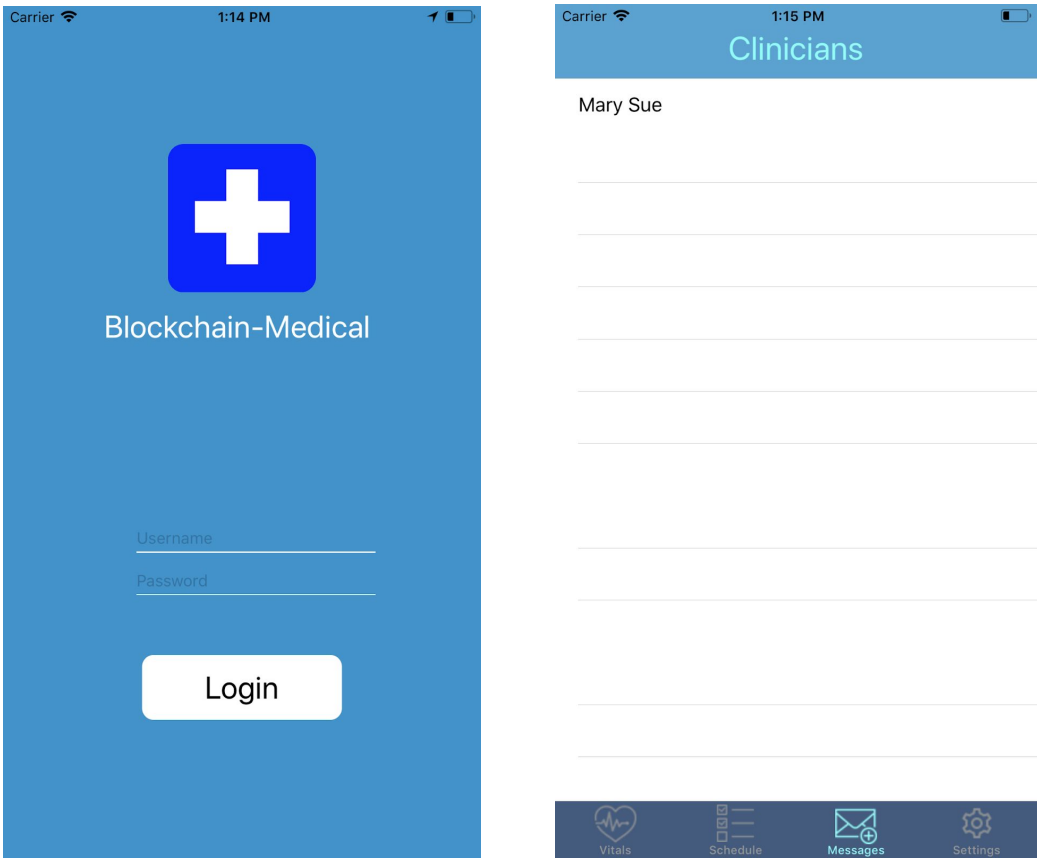

Figure 3: Login Screen, Messaging Tab

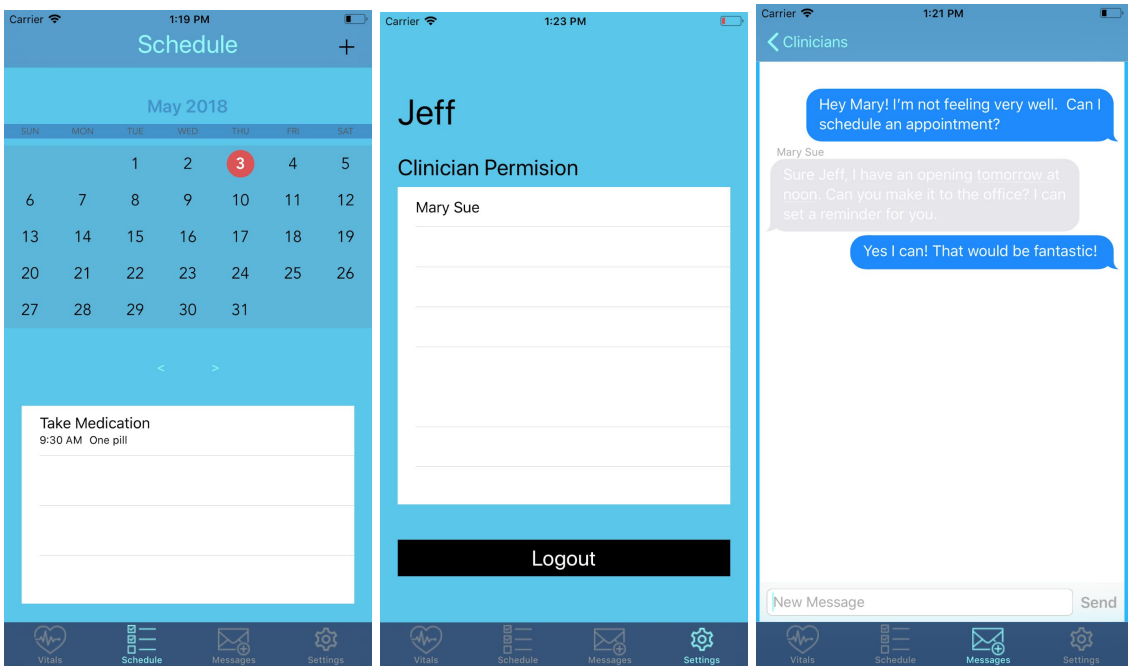

Figure 4: Schedule, Permissions, Messaging

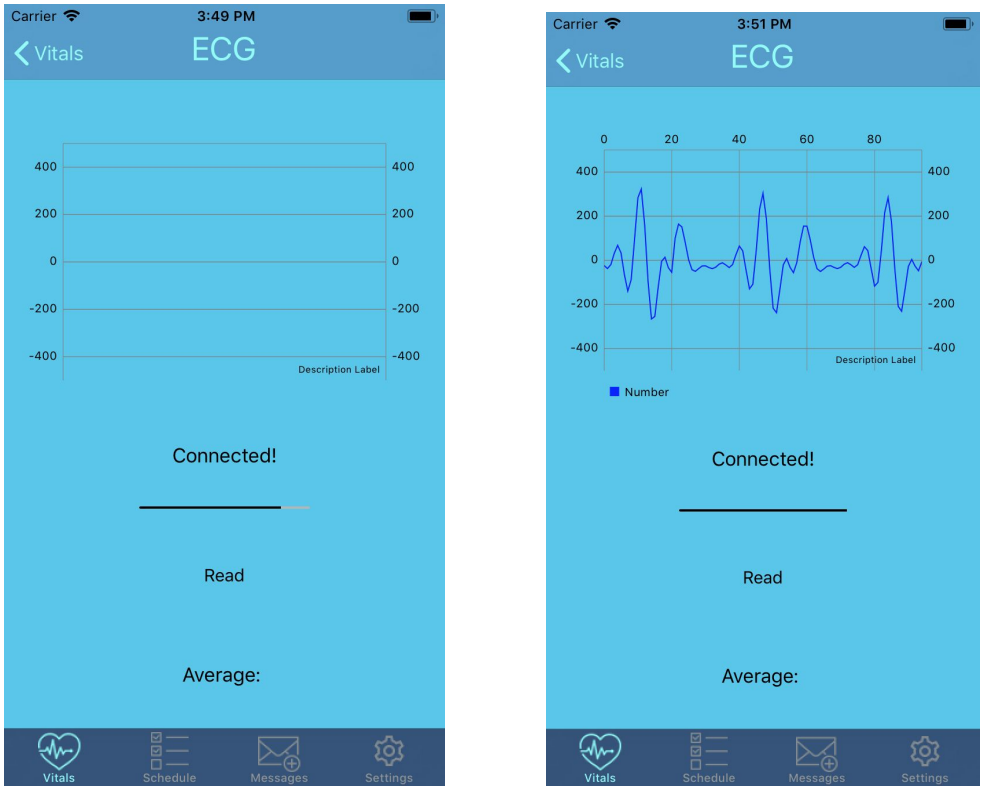

Figure 5: Vitals

Substantial Equivalence Comparison

Our proposed “new” device is substantially equivalent to the VitalConnect Platform (#k141167). The following table summarizes the substantially equivalent components of our “new” device and the VitalConnect Platform.

Category	Blue Health	VitalConnect Platform
Intended Use	The Blue Health app and device is intended to be used to improve communication and monitoring between clinicians and patients at home by utilizing vital data collection, messaging, and	The revolutionary Vista Solution™ platform from VitalConnect is set to change the nature of patient care in hospitals and healthcare facilities around the world. The platform contains the

	reminders.	VitalPatch, an elegantly designed biosensor, that sends vital sign data seamlessly to remote caregivers, giving them a powerful view into the critical readings that have a direct impact on patient care.
Target Population	The Blue Health app and device target population consists of at home patients and their clinicians.	Both inpatient and outpatient care and monitoring
Use Location	The Blue Health app and device will be used patients at home and their clinicians at practices/hospitals.	The VitalConnect Platform is to be used in both hospital applications and at the home by patients and clinicians.
Performance	The Blue Health app and device is a robust system will all appropriate failsafes implemented in order to create an optimal experience for both the patients and the clinicians. Our system specializes in real time data collection and display, which the patient can later choose to send to their clinician.	Provides real-time monitoring of eight measurements for in hospital and home usage.
Electrical Safety	Yes.	Also yes.

A Reflection

Although we are happy with our product as is, there was more to our vision. Due to the reality of the situation, we are all students and all have outside responsibilities, other classes, and unpredictable circumstances always arise.

The problem we saw was that there is a growth of people that want to monitor their health from their own home. With a growing pressure to prevent medical problems instead of cure them, monitoring has become the most important step in maintaining health. We wanted to help provide a more cost efficient and easy to use solution to this problem, given that traditional patient monitors are bulky and expensive. We wanted to provide historical data and an easy to use interface for the patient to have control of their own data. Our solution was mainly centered around communications. We wanted to allow patients to safely send their vital data to their clinicians and be able to open dialogue between them. We think it is very important that patients are able to communicate with their doctors and that patients can send their vitals from their home instead of having to take a trip to the doctors every time the doctors wants to check in on them. An important feature of the app we created was the messaging tab, giving the patient more control over what they want to send. Another important feature we considered was having all of this information in one place. The patient can contact their doctor, take their vitals, and see a list of important reminders on a calendar. Centralizing all of this again allows the patient to take control over their day to day health and make it easy to monitor.

Looking back, we accomplished a lot over the course of the semester, even if we didn't reach our final design goals. Nobody in our group had ever touched swift before this semester, and we certainly had never processed medical waveforms. Over the course of the semester, we were able to construct an app to monitor an array of different vital signals, which was the basis of the problem we were trying to solve. In addition to that, we chose to focus on communication between patient and clinician while giving the patient full control over their personal data and vitals. At the very end of this semester, we were able to allow the patient to specify which clinician had access to their vitals, but it was a very binary option. Either the clinician would have access to all the patient's historical and vital data, or none at all. If we could allow more specialized access to vitals (i.e. patients can specify which particular vitals they wish to share), we think it would be a better user experience that respects patient privacy. An ideal situation something like the following. A clinician logs onto the app looking for one of their patients vitals, but notices that they do not have permission to view that specific vital. The clinician can then go into the messaging section of the app and send a message to the patient requesting access to a specific vital. The patient then would receive a push notification from their clinician, and could go into the app and set the permission for that specific vital so that their clinician can see their data.

Also, we would have liked to added some more functionality to the remainders. Currently, both the patient and clinician can create one reminder at a time for the patient to see. We would have liked to investigate implementing repeated reminders for such use cases as taking pills everyday. Additionally, we would have liked to implement something to differentiate between patient created reminders and clinician created reminders, as well as a way to filter between viewing the multiple sets of reminders. Also, if there are multiple clinicians for the same patient, ideally they would all have a different color or something on the patients calendar. This way, the patient can clearly see what each of their clinicians is trying to communicate to them.

While we are very pleased with how our app handles streaming of the vital signals and displaying them, right now our software is not robust enough to deal with hardware failures. Unexpected or faulty data streamed from the rPi can cause app crashes or issues in performance. Given more time, including more run-time checks to ensure smooth functionality (avoiding crashes or unintended performance) would definitely be a priority, but we are overall happy with how our app handles expected data and properly functioning hardware.