# RhythmGuard

*Happy Heart, Happy Life*

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# Problem

**In 2016, 9.3 million Americans had Atrial Fibrillation & the incidence in increasing**

**In 2005 over 5 million outpatient visits per year were related to diagnosis, monitoring and treatment of Atrial Fibrillation**

CDC

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# Current AFib Diagnosis & Monitoring

**Traditional ECG**: One time in office or in hospital use

**Holter Monitor**: 4-10 day at home monitor

**Implantable Loop Recorder**: Surgically placed device that provides constant monitoring with up to 3 years battery life

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# Shortcomings of Current Monitoring

No at-home, long-term, constant-use monitoring device

Studies with implantable devices show that over 40% of patients will have episodes of atrial fibrillation missed with traditional non-continuous monitoring

15% of patients with adequately treated atrial fibrillation will re-develop atrial fibrillation after 3 months

## Solution:

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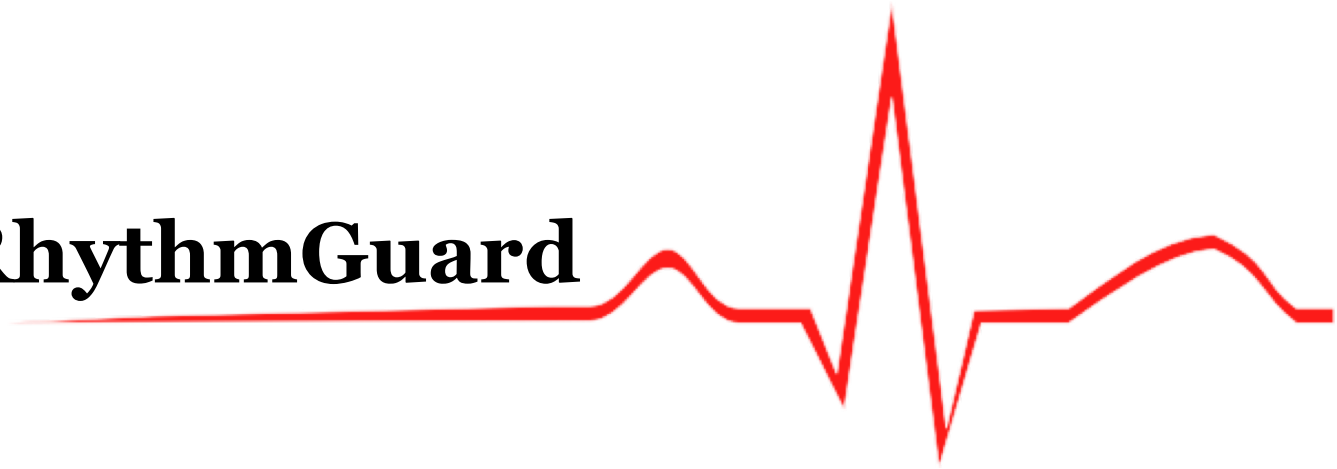

**Improved diagnosis & monitoring of Atrial Fibrillation**

**At-home & On-the-Go**

1. **Comfortable, Convenient & Continuous**
2. **Improved diagnosis and medical management**
3. **Automatic communication with Primary Care Physician**

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# Solution

## Advantages:

- Light-weight and streamlined hardware
- Integrates with current smartphone software
- Cost-friendly, single-use, water resistant electrodes
- Simple graphical user interface with large font
- Skilled physician provider team with access to EHR

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# Solution

## Advantages:

- Integrates comfortably into day-to-day living
- Eliminates hassle of extraneous software devices
- Eliminates indecision and stress of contacting emergency services of PCP
- Reduces technological learning curve with simple interface

# Direct Competition

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| Technology | Use at Home | Constant & Comfortable | Automatic PCP Alerts |
|---|---|---|---|
| RhythmGuard  | ✓ | ✓ | ✓ |
| AliveCor® | ✓ | ✗ | ✓ |
| Implantable Recorders | ✓ | ✗ | ✓ |
| Holter Monitor | ✓ | ✗ | ✗ |

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# Market Opportunity

**Targets (USA):**

**Phase 1 - Patients with known Afib (4 million people):**

4 million x $5/month x 8% market share = $19 million/year

**Phase 2 - Patients at risk of Afib (15 million people):**

15 million x $5/month x 3% market = $27 million/year

**Combined phase 1 & 2 opportunity = $46 million/year**

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# Business Model

## Subscription Based

**We plan to set up customer lists via healthcare providers and will have them subscribe to monthly shipments of electrode tips as well as a monthly fee for our proprietary mobile application**

**The customers will have a one-time purchase of the wires and transmitter necessary to connect the electrodes and mobile app**

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# Business Model

## Subscription Based

**$5/month = $60/year/patient**
**Self-Pay – peace of mind**
**Insurance pay – reduce hospital admissions**

- Patients w/ afib → 1 in 222 patients will have intracranial hemorrhage/year while on anticoagulation → $30K/admission
- 222 patients x $60/year = $13K
- 1 hospital admission/year = $30K

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# Reimbursement Model

**We will work with insurance companies to offer a rebate to their customer base for utilizing our product**

**Current Afib patient healthcare expenditures: $8,705/year more than non Afib patient – mostly due to inpatient services**

**Able to reduce hospitalization and inpatient care cost by 1% = reduction in health care burden of $260 million/year**

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# Technology Validation

**We will utilize:**

- **established electrode technology**
- **bluetooth data transmission**
- **Proprietary software algorithms and mobile application code**

**We will validate our technology by testing in pre-clinical models of AFib and then in patients diagnosed with persistent AFib**

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# Customer Validation

**We will survey AFib patients hospitalized at institutions with operational cath labs before and after device placement to assess their willingness**

**We will follow these surveyed patients (via cardiology office visits) to assess the maintenance of willingness over the course of 1 year**

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# Regulation Hurdles

**Pursue a 'Substantial Equivalence' plan with the FDA**

**Predicate Device: Apple iWatch/AliveCor Kardiaband**

**FDA 510K costs class II device:**

- **Approval application in other country (Canada) - $20,000**
- **Consulting - $16,000**
- **Device Review Fee - $3,000**
- **Registration Fee - $5,000**

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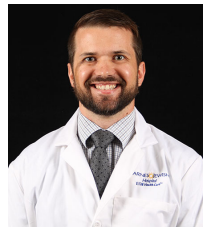
# Leadership Team

Ike Chinyere MD/PhD Candidate

David Margolis MD/PhD – Hand Surgeon & Biomedical Engineer

Joshua Uhlorn PhD Candidate & McGuire Entrepreneurship Graduate

Daniel Crawford MD – Radiology Resident & Biomedical Device Engineer



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# Potential Exit

**We will seek to be purchased by Alphabet and incorporated into Google Pixel phones to compete with Apple's iWatch AFib technology**

**Estimated Company Value @ 10 years: $410M**

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# Financial Management

**We will seek:**

1. **SBIR/STTR grants to begin work**
2. **Minimally dilutive funding to break-through the initial market**
3. **Angel Investments to scale once we reach $2M in profits**

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# Risk Mitigation

**We will set up an operational system to sequentially identify risks and successfully mitigate with preliminary data and advisor insight**

**Risk 1: Customer Discovery**
**Risk 2: Viable Business/Reimbursement Model**
**Risk 3: Ability to Scale**

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# Conclusion

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**Improved AFib treatment efficiency and diagnosis through**

**At-home ECG Monitoring**

1. Comfortable and Convenient
2. Automatic communication with Primary Care Physician
3. Improved over current technologies with decreased cost

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