



monitor ai

MonitorMed AI: Application & Market Risk Analysis

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Jules & Ken

MonitorMed AI

Non-Intrusive Performance Monitoring for FDA-Approved Medical AI

The Challenge

950+ FDA-approved AI medical devices with no performance monitoring

- Can't modify validated models
- Performance degradation unknown
- No traditional MLOps possible

Our Solution: AI model monitoring

- 92% accurate uncertainty estimation
- Zero modification to FDA models
- 23% reduction in false positives

Target Market

8,000+ Radiology practices in US

950+ FDA-approved AI devices



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Market Opportunity Analysis



Healthcare **AI Monitoring** Market Overview

1. Medical AI market projected to reach \$200B by 2030
 2. 950+ FDA-approved AI medical devices in use with minimal performance monitoring.
 3. Only 44% of hospitals evaluate AI models for bias, highlighting monitoring gaps.
 4. FDA signaling increased scrutiny on AI/ML device performance post-approval
 5. Emerging regulatory frameworks emphasizing continuous monitoring of medical AI/ML
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Primary Market Segments (TAM, SAM, SOM)

1. Hospital Compliance Market (Primary)

- TAM: Global AI healthcare compliance market projected to reach \$7B by 2028 (CAGR 24%)
- SAM: \$480M (2,000+ hospitals using multiple AI diagnostic tools). 79% of healthcare organizations now use AI, with \$3.20 ROI per \$1 invested
- SOM: \$24M (100 hospitals in first 3 years)
- Growth drivers: Regulatory pressure, risk management, patient safety

2. Healthcare Liability Insurance Market

- TAM: \$800M (insurers covering AI diagnostic risks). AI reduces malpractice risk by 23% in early testing
- SAM: \$240M (insurers with radiology practice specialization)
- SOM: \$12M (risk management partnerships with 3-5 major insurers)
- Growth drivers: Malpractice risk reduction, premium optimization

3. Radiology AI Vendor Market

- TAM: \$350M (150+ AI medical device vendors). Global AI radiology market expected to hit \$1.5B by 2027
- SAM: 70M (30+ vendors with FDA-approved products)
- SOM: \$7M (partnership with 5-8 vendors in years 2-4)
- Growth drivers: Competitive advantage, FDA compliance, performance validation

Competitive Landscape Analysis

Direct Competitors

1. Traditional MLOps Platforms (DataRobot, Weights & Biases)

- Strengths: Established platforms, strong data science adoption
- Weaknesses: Not FDA-compliant, require model modification, no healthcare specialization
- Our advantage: Non-intrusive monitoring that maintains FDA validation

2. Healthcare AI Validation Tools (Rhino Health, Centaur Labs)

- Strengths: Healthcare focus, data annotation capabilities
- Weaknesses: Focus on pre-approval validation, not continuous monitoring
- Our advantage: Post-approval performance monitoring in production environments

3. In-house Hospital Monitoring Solutions

- Strengths: Tailored to specific institutional workflows
- Weaknesses: Resource-intensive, inconsistent methodologies, limited expertise
- Our advantage: Standardized approach, compliance-focused

Indirect Competitors

Explainable AI Solutions (Fiddler AI, Arthur AI):

- Strengths: Growing adoption, focus on AI transparency
- Weaknesses: Often require model access/modification, not healthcare-specific
- Our advantage: Healthcare-specific, FDA-compliant, quantifies uncertainty

Manual Auditing Services:

- Strengths: Human expertise, established healthcare relationships
 - Weaknesses: Labor-intensive, expensive, reactive rather than proactive
 - Our advantage: Automated, continuous monitoring, early warning system
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Market Entry Strategy & Risks

Go-to-Market Strategy

Phase 1: Hospital Compliance Beachhead (Months 0-12)

- Target 3-5 academic medical centers for pilot implementation (Possibly UPMC)
- Focus on radiology AI monitoring for FDA-approved algorithms
- **Validate value proposition:** regulatory compliance + performance improvement.
- 23% reduction in false positives (early testing, from open-source datasets and models).

Phase 2: Expansion to Integrated Delivery Networks (Months 12-24)

- Expand within health systems
- Develop case studies demonstrating ROI and patient safety improvements
- Begin outreach to healthcare liability insurers with proven results
- Key performance metric: 5+ full enterprise deployments

Phase 3: Insurance Partnerships & AI Vendor Integration (Months 24-36)

- Establish partnerships with 2-3 healthcare liability insurers
- Create premium discount incentives for hospitals using MonitorMed
- Begin integration with AI vendors seeking competitive differentiation
- Key performance metric: 2+ insurer partnerships, 3+ vendor integrations

Market Adoption Risks & Mitigations

1. Hospital Budget Constraints

- Risk: Lengthy sales cycles, competing budget priorities
- Mitigation: Demonstrate clear ROI through reduced errors and liability
- Contingency: Develop lightweight version with lower entry cost

2. Multi-stakeholder Decision Process

- Risk: Multiple departments involved (IT, Radiology, Compliance)
- Mitigation: Tailored value propositions for each stakeholder
- Contingency: Focus on compliance champions as primary advocates

Market Adoption Risks & Mitigations

3. Resistance to New Monitoring Layer

- Risk: IT departments hesitant to add another monitoring system
- Mitigation: Design low-footprint integration requiring minimal IT resources
- Contingency: Develop standalone version with manual upload capabilities

4. Insurer Partnership Complexity

- Risk: Complex and lengthy partnership agreements
- Mitigation: Start with pilot programs for high-risk imaging protocols
- Contingency: Focus on direct hospital sales while building insurer relationships

Unique Value Proposition & Differentiation

Why We Win: Key Differentiators

1. Regulatory & Clinical Focus

- Built for FDA-approved medical AI validation
- Maintains regulatory compliance while providing performance insights
- Non-Intrusive Technology

2. Zero modification to FDA-validated models

- Monte Carlo Dropout methodology for better uncertainty estimates
- Integrated Risk Assessment

3. Combines technical performance with clinical context assessment

- Provides actionable insights to compliance teams and radiologists
 - 23% reduction in false positives in early testing
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Value Creation For Key Stakeholders

- Hospital Compliance Teams: Continuous validation, regulatory audit trails, early detection of model degradation
- Healthcare Insurers: Reduced liability exposure, data-driven risk assessment, hospital incentive mechanisms
- Radiologists: Increased AI confidence, prioritized case reviews, improved workflow efficiency

THANKS

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