



MyMR®

# Regulatory Statement of Non-Device Status

*For MyMR AI Patient Education and Explanation Tools*

**Company:** MyMR (Medinex Corp.)

**Subject:** Determination of non-device status under FDA Digital Health Policy

**Date:** October 11<sup>th</sup>, 2025

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## 1. Purpose

This document establishes that the **MyMR patient-facing AI modules**—including *Andrea, Rebecca, Robert and related educational tools*—are **not classified as medical devices** under U.S. Food and Drug Administration (FDA) regulations. These tools provide **clinical decision support (CDS) for patients and caregivers** by enhancing understanding of their existing clinical data, without independently diagnosing, treating, or preventing disease.

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## 2. Regulatory Framework

Under **Section 520(o)(1)(E)** of the **Federal Food, Drug, and Cosmetic Act (FD&C Act)**, as amended by the **21st Century Cures Act (2016)**, software functions are excluded from the definition of a “device” if they:

1. Display, analyze, or print medical information about a patient;
2. Support or provide recommendations to a health-care professional regarding prevention, diagnosis, or treatment; and
3. Enable the health-care professional (or patient) to **independently review the basis** for such recommendations.

Additionally, the FDA’s guidance “**Clinical Decision Support Software**” (**September 2022**) clarifies that **patient-directed educational tools** are generally **non-device CDS** when they merely **translate, contextualize, or summarize existing clinical data** for comprehension and engagement.

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### 3. Description of the MyMR AI Toolset

- **Function:** Natural-language explanations of lab results, medication lists, discharge instructions, and care-plan summaries derived from FHIR-based EHR data and claims.
  - **Output:** Plain-language educational summaries, general wellness information, and references to authoritative medical sources.
  - **Intended Use:** To help patients better understand data generated by their health-care providers—not to provide new medical interpretations or treatment advice.
  - **Scope:** Consumer-facing web and mobile modules accessible via the MyMR PHR platform.
  - **Users:** Patients, caregivers, and laypersons seeking to understand provider-authored health information.
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### 4. Rationale for Non-Device Classification

Criterion	Regulatory Basis	MyMR Compliance
1. No independent diagnostic or treatment claims	21 U.S.C. § 321(h); FD&C Act § 201(h)	The AI provides explanations only; it does not diagnose, predict, or recommend specific treatments.
2. Human interpretability and transparency	21 U.S.C. § 360j(o)(1)(E); FDA CDS Guidance § III(B)(2)	Each output cites data sources and reasoning so patients can review the factual basis.
3. Consumer educational intent	FDA CDRH Digital Health Policy (2022–2024)	The software’s stated purpose is health education, literacy, and engagement, not clinical decision-making.
4. No connection to life-supporting systems	21 CFR § 862–892 classification framework	The tool operates independently from medical hardware or diagnostic devices.
5. Low risk to patient safety	FDA Risk-Based Policy for CDS	Misinterpretation poses no direct harm; users are instructed to consult clinicians for decisions.

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### 5. Disclaimers and Labeling

MyMR displays the following disclosures to users:

- *“This AI tool is for educational and informational purposes only. It does not provide medical advice, diagnosis, or treatment. Always consult your health-care professional for questions about your care.”*

- *“MyMR summarizes information from your medical records but does not alter or replace data from your clinician or EHR.”*
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## 6. Quality and Compliance Commitments

- Follows **FDA Digital Health Policy for Device Software Functions (DSF)** best practices for non-device functions.
  - Implements **CARIN Code of Conduct** for data stewardship.
  - Maintains **HIPAA and FTC** compliance for privacy and consumer transparency.
  - Engages periodic legal review to ensure continued exemption eligibility as regulations evolve (e.g., TEFCA and CDS framework updates).
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## 7. Conclusion

Based on current FDA law and guidance, **MyMR’s patient-facing AI explanation tools** constitute **non-device Clinical Decision Support (CDS) software** because they:

- Serve an **educational purpose only**,
- **Do not generate clinical recommendations or diagnoses**,
- Allow users to **independently verify underlying information**, and
- Pose **no direct patient-safety risk**.

Accordingly, they are **exempt from FDA medical-device premarket review and do not require clearance, De Novo, or 510(k) authorization**.

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