2-19-25

FDA Class I Registration for ChatMD

Company Information

- **Company Name:** ChatMD
- **Address:** 328 S. Michigan Street, Plymouth, IN 46563, United States
- **FDA Registration Number:** 3032847781
- **Owner/Operator Number:** 10091612

FDA Class I Medical Device Registration

ChatMD is officially registered with the U.S. **Food and Drug Administration (FDA)** as a **Class I medical device** under **21 CFR 801** regulations. This registration confirms compliance with general controls and regulatory requirements applicable to medical devices classified under **Class I, 510(k)-Exempt**.

Regulatory Compliance and Listing Details

As an **FDA-registered** establishment, ChatMD ensures adherence to the following regulatory requirements:

- **Medical Device Reporting (MDR):** ChatMD maintains a system for reporting adverse events and device malfunctions per **21 CFR 803**.
- **Labeling Compliance:** All ChatMD labeling and packaging meet FDA requirements under **21 CFR 801**, including proper device identification, manufacturer details, and instructions for use.
- **Quality System Regulations (QSR):** Although ChatMD qualifies for **partial exemptions** from certain Quality System Regulations (QSR) per **21 CFR 820**, the company follows strict **SaMD (Software as a Medical Device) development and compliance protocols** using **Greenlight Guru**.
- **Establishment Registration & Device Listing:** ChatMD is registered with the **FDA's Establishment Registration & Device Listing** database, confirming its active status.
- **Import & Regulatory Compliance:** ChatMD follows all relevant FDA regulations regarding **medical device imports, marketing, and sales** within the United States.

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Intended Use and Scope

ChatMD is an **AI-driven telemedicine platform** designed to assist in the **symptom assessment and prescription of treatments for select acute infections** through ChatRx. It operates as an **FDA Class I, 510(k)-Exempt medical device**, designed for informational purposes and to facilitate access to licensed healthcare providers via telehealth.

Contact Information for FDA Inquiries

For further information regarding ChatMD's **FDA registration and compliance**, please contact:

📧 **Email:** reglist@cdrh.fda.gov
📞 **Phone:** 301-796-7400 (Option 1)

For additional regulatory guidance, visit the **FDA Establishment Registration and Listing** page.