2-19-25

Regulatory Compliance Features: FDA Class I Medical Device Compliance

Device Name

- **Purpose**: Clearly and prominently display the product name, emphasizing its intended use and ownership.
- **Example**:
    - *ChatMD*

Model Identification

- **Purpose**: Include specific model or version details to ensure traceability and distinguish product iterations.
- **Example**:
    - *ChatRx 1.0.yymmdd*

Nomenclature for Version or Model Numbering in SaaS Products

1. **Semantic Versioning**:
2. The version number scheme of **v0.0 build yymmdd** where **0.0** is the major and minor product version and **yymmdd** is the date the build was released in **two digit year**, **month**, and **day** format
3. **`Semantic Versioning:`** `Use a three-part version number format: Major.Minor.date`
4. **Major Version:** Increment when there are significant updates, feature additions or changes that may affect compatibility or functionality.
5. **Minor Version:** Increment for minor feature additions or enhancements that do not fundamentally change the product.
    a. **Example:** 1.0.250215

Manufacturer Information

1. **Owner**:
    a. **Company Name**: ChatMD
    b. **Address**: 328 S. Michigan Street, Plymouth, IN 46563
    c. **Contact**: Tod Stillson MD (clinical@chatrx.net)
    d. **Role**: Owner and operator of the ChatRx medical device.
2. **Development Partner**:
    a. **Company Name**: Smart Data Enterprises Inc.

b. **Address**: 151 E 85th Street, #9D, New York, NY, United States
c. **Contact**: info@smartdatainc.net
d. **Role**: Responsible for engineering and software development.

1. Understand the Scope of Exemptions

1. **Premarket Notification (510(k)) Exemption**:
    a. ChatMD qualifies as a Class I exempt device, confirmed by referencing the FDA's Classification Database.
    b. The exemption process was completed by the Rapacke Law Group during the device's 2024 registration.
2. **Quality System (QS) Exemption**:
    a. While exempt from some Quality System Regulations (QSR), requirements for records, complaint handling, and device maintenance still apply.

2. Comply with General Controls

1. **Establishment Registration and Device Listing**:
    a. **Registration Details**:
        i. Registered on: *12-8-2024*
        ii. **Company**: ChatMD
        iii. **Address**: 328 S. Michigan Street, Plymouth, IN 46563
        iv. **Registration Number**: 3032847781
        v. **Owner/Operator Number**: 10091612
2. **Labeling Requirements**:
    a. Ensure compliance with FDA regulations for branding, intended use, and cautionary statements.
3. **Medical Device Reporting (MDR)**:
    a. Implement robust systems for reporting adverse events, as required by the FDA's MDR program.

3. Implement Quality System Practices (Greenlight Guru)

1. **Record Maintenance**:
    a. Maintain comprehensive records of design and production processes.
2. **Complaint Management**:
    a. Establish systems for documenting and resolving complaints, as well as implementing corrective actions.

3. **Internal Audits**:
    a. Schedule quarterly internal audits, with the first audit completed three months post-registration.

4. Maintain Design Controls

1. **Best Practices for Software-Driven Devices**:
    a. Validation and verification of software to ensure safety and effectiveness.
    b. Documentation of tests confirming the device meets its intended use.

5. Conduct Annual Device Registration

- **Annual Fee**: Pay the FDA Establishment Registration Fee of $9,280 annually.
- **Renewal**: Ensure timely renewal of both registration and device listing.

6. Monitor Regulatory Changes

- **Purpose**: Stay informed of any changes to FDA regulations or guidance that might affect the exemption status of ChatMD.
- **Implementation**: Regularly review updates on FDA's official website or subscribe to regulatory bulletins.