*In proceedings of IEEE International Conference on Digital Health (ICDH) , 2024 at IEEE World Congress on Services 2024*

# Semantically Rich Approach to Automating Regulations of Medical Devices

Subhankar Chattoraj, Redwan Walid, and Karuna Pande Joshi
*Department of Information Systems, University of Maryland Baltimore County, Baltimore, MD 21250, USA*

***Abstract*—Advanced medical devices increasingly use sophisticated AI/ML models to enable real-time analytics for monitoring patients. In the US, these AI models, which often form the underlying device software, are regulated by the Center for Devices & Radiological Health (CDRH) at the Food & Drug Administration (FDA) to ensure the safety & efficacy of the medical device. These regulations for medical devices are currently available as large textual documents, called Code of Federal Regulations (CFR) Title 21, that cross-reference other documents & so require substantial human effort to parse & comprehend. Hence, the device manufacturers incur significant costs during the regulatory process to adhere to all the rules & policies laid down by the FDA. We have developed a novel, semantically rich approach to extract the knowledge from the rules & policies for Medical devices & translate it into a machine-processable format that can be reasoned over. This framework was developed using AI/Knowledge Management approaches & Semantic Web technologies like OWL/RDF & SPARQL. This paper presents the detailed Ontology/Knowledge graph we developed for medical device regulations & the Use case results that validate our design. Regulators & manufacturers alike can use our framework to significantly reduce the human effort required during the device regulatory process.**

***Index Terms*—semantic web; knowledge graph; medical device; compliance; code of federal regulations.**

## I. Introduction

With the explosion of Internet of Things (IoT)- based sensors in state-of-the-art medical devices, sophisticated Artificial Intelligence/ Machine Learning (AI/ML) models are rapidly being integrated into these devices to facilitate real-time analytics & monitoring of patient's vitals. Device manufacturers are developing AI/ML models that are often designed to take advantage of the algorithms' self-learning capabilities. These new models are now fueling the need to revise the existing processes in medical device approval & post-market surveillance systems.

The U.S. FDA in the early 20th century was entrusted with the crucial task of ensuring the safety & efficacy of drugs before they could be marketed [1]. Later, amendments made to the Federal Food Drug & Cosmetics Act in 1976 broadened the scope of the FDA's responsibilities to include overseeing the safety aspects of medical device development [2]. Medical devices fall under the FDA's CDRH jurisdiction. As defined by the Federal Food Drug & Cosmetics Act, a device encompasses various forms such as implements, instruments, contrivances, apparatuses, machines, implants, or in vitro reagents. Medical device cannot achieve their intended purpose through chemical action or dependence on metabolism. Additionally, certain products containing biological material, such as acellular dermatologic fillers, which are inert, may also fall under the classification of medical device [3]. The FDA's definition of medical device covers a wide range of devices encompassing a wide array of objects ranging from simple tools like tongue depressors & stethoscopes to more complex equipment such as life-support devices like pacemakers, ventilators, laboratory apparatus, surgical instruments [4].

Regulatory policies for medical devices are currently available as large textual documents that often cross-reference each other. These documents are usually not machine-processable & require substantial human effort to parse & comprehend. Hence, device manufacturers incur significant costs to adhere to all the rules & policies laid down by the FDA during the regulatory process. We have developed a novel, semantically rich approach to extract the knowledge from the rules & policies for medical devices & save them in a machine-processable format of Knowledge Graph (KG) or Ontology. This medical device regulation KG can be queried & reasoned over to identify complex rules that apply to medical devices. Our framework was developed using AI Knowledge Management approaches & Semantic Web technologies like OWL/RDF & SPARQL. This paper presents our approach in detail along with the validation results. Our design will help automate the pre-market analysis of 1,700 distinct types of devices regulated by FDA, which are arranged into 16 medical specialty "panels". We have validated our compliance KG using the cardiovascular device Part 870 [5]. Figure 2 gives an overview of the proposed architecture. The main contributions of this paper are as follows:

- A semantically rich machine-processable medical device compliance KG aims to automate the device classification & CFR, allowing the machine-processable model to reduce manual effort & decrease overall cost, approval time, & time-to-market.
- To the best of our knowledge, the presented work is the first to incorporate semantically rich machine-processable compliance KG in automating regulations of medical devices.

In this paper, we discussed the related work in section II. Our semantically rich machine-processable compliance KG methodology is presented in section III. The experimental evaluation & validation of the proposed KG are described in Section IV. The conclusion & future work in defined in section V & VI.

Table I
MEDICAL DEVICE CLASS AND REGULATORY PATHWAY DC: DEVICE CLASS

| Risk Categorization | DC | Overview & Regulatory Pathway |
|---|---|---|
| Low-Risk | Class I | This category constitutes 47% of all medical devices, with 75% of devices within this classification being exempted from the approval process. Example surgical scalpels, crutches, hospital beds [6] [7]. |
| Medium-Risk | Class II | These devices are categorized as medium-to-higher-risk [8]. This class accounts for 43% of all medical devices [9]. They are subject to general & special controls to ensure adequate safety & efficacy. The majority of devices in this class will need to undergo a PMN application. Example diagnostic endoscopes, colonoscopes, AI software [6] |
| High-Risk | Class III | This category encompasses 10% of the medical devices regulated by the FDA. These devices necessitate a PMA process & undergo other critical steps before being licensed. Example silicone implants, implanted pacemakers [10]. |

## II. RELATED WORK

### A. FDA Device Classification

The Code of Federal Regulations (CFR) serves as a fundamental set of documents within the Executive Branch of the U.S. government [11]. It offers the public a thorough repository comprising all rules issued by the president & government agencies [12]. These documents play a vital role in the functioning & communication of the government, providing essential guidelines & standards for various operations & activities. In accordance with the CFR -Title 21 Parts 800-1050 (800-161 cross-cutting device & 862-1050 device-specific requirement) covers all medical devices [13]. The FDA categorizes devices into three groups based on the risk: Class I, II, & III.

Typically, the process of approving new drugs averages around 12 years, whereas bringing new medical devices from concept to market typically takes between 3 to 7 years [14]. The approval process is cumbersome & the time for approval may increase depending on the FDA workload [15]. The classification & exemption based on the regulatory pathway given in Table I required a review of all the devices based on the specific category. Understanding the CFR code is also critical for the sponsor seeking clearance to adhere to the regulatory guidelines. The process is time-consuming & not machine-processable & is solely available in textual format, necessitating substantial manual effort to parse their rules & constraints, resulting in increased overall cost & time-to-market.

### B. Semantic Web

Artificial intelligence (AI) & related technologies are becoming increasingly prevalent in healthcare [16] [17]. Numerous research studies suggest that AI has the potential to perform as well as, or even better than, humans at various critical healthcare tasks, including disease diagnosis [18] [19]. However, the rapid adoption & integration of AI into healthcare systems raise significant ethical & legal challenges. Regulations are necessary to tackle the unique challenges & considerations associated with AI applications in healthcare. FDA has outlined Medical Device Action Plan [20] for AI/Machine Learning-Based Software. This initiative aims to provide a framework for regulating AI-based medical software to ensure its safety, effectiveness, & reliability in clinical settings. The understanding of such regulatory guidelines is crucial for device manufacturers seeking clearance & adhering to the regulations outlined by the regulations.

One potential solution to this challenge is to leverage Semantic Web techniques for modeling & reasoning about the regulation policies. By employing these techniques, we can develop a KG that captures & represents the relationships between different entities, policies, & regulations related to device classification & necessitate 510(k) clearance. The KG facilitates interoperability, understanding, & compliance with data protection regulations in a distributed & dynamic environment. The Semantic Web primarily focuses on data rather than documents. Semantic Web technologies encompass languages such as the Resource Description Framework (RDF) [21] & the Web Ontology Language (OWL) [**?**], which are used for defining ontologies & representing metadata based on these ontologies. Additionally, Semantic Web tools enable reasoning over these descriptions. These technologies play a crucial role in supporting common semantics of regulatory policies such as CFR, allowing all agents familiar with basic Semantic Web technologies to utilize service data efficiently. In this work, we are mainly focusing on automating the device classification based on risk category & CFR, which is very crucial to reducing the overall cost & time-to-market.

### C. Health data Compliance using Knowledge Graph

In previous research, semantically rich knowledge graph (KG) has been potentially utilized in multidisciplinary domains from drug discovery & predictions to health-care compliance [22], [23]. In earlier research, KG contained various encapsulated rules for machine-processable compliance. These initiatives aimed to automate the continuous monitoring of data operation, transfer, & sharing [24].

In a study the KG developed for automating regulation-compliant cloud services, based on the Health Insurance Portability & Accountability Act (HIPAA), is a comprehensive ontology that outlines three main hierarchical categories: Privacy rule, security rule, & stakeholders [25]. In another study, a KG was developed specifically to describe COVID-related security & privacy rules, drawing from the framework established by HIPAA. This ontology not only builds upon the HIPAA ontology but also contributes to the automation of

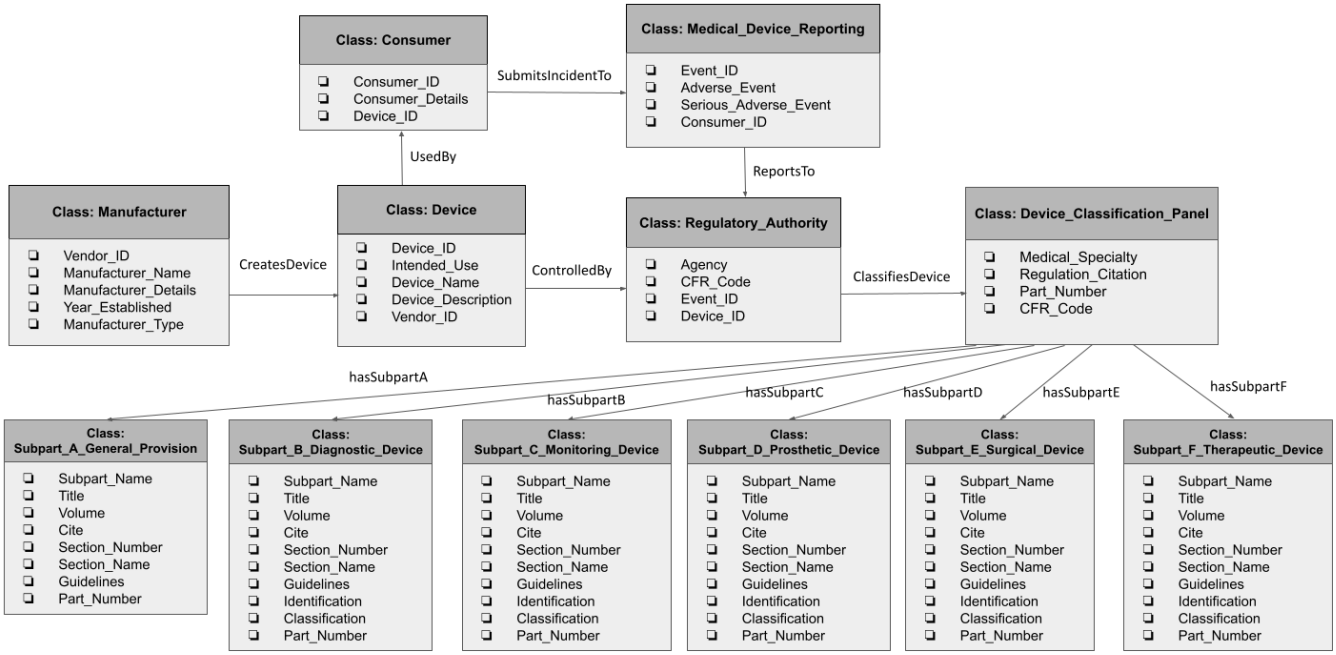


Figure 1. Comprehensive Knowledge Graph for the CFR -Title 21 includes key classes and properties related to medical devices

HIPAA guideline adherence in accessing patient records [26]. In another study, Semantic Web & Ethereum Blockchain were integrated to enforce data protection regulations [23] while the attribute-based encryption schemes in securing healthcare systems were also proposed [27]. The prior works have also proposed KG-based approaches to enforce data protection policies [28], [29].

## III. Methodology

In this section, we describe our framework in detail, including the techniques we used to create the KG, which captures the overall structure of CFR along with key instances. In Figure 2, the overall architecture is illustrated. The KG is constructed using the CFR - Title 21 Part 862 - 892 comprising of the 1700 distinct devices risk category & requirement for 510(K) notification requirement or pre-market approval [30]. The following section illustrates the construction & population of the CFR -Title 21 Knowledge Graph.

### *A. Building CFR -Title 21 Knowledge Graph*

The KG was created by referring to the overall document structure rules & provenance embedded in the CFR -Title 21 from Parts 862-892. In the CFR -Title 21, there are 18 medical specialties. Each medical specialty comprises multiple subparts. The subparts consist of general provision & five different device categories: diagnostic, monitoring, prosthetic, surgical, & therapeutic devices. There are 1700 distinct devices for all the device categories. The main attribute captured includes the classification of the device, Title, volume, cite, section, part number. The primary node describes different Subpart of devices as mentioned in Figure 1. to indicate the regulatory classification of devices under specific subparts. Each device node has additional attributes representing specific information about the device, such as Identification, Classification, device name, & references to relevant regulations (e.g., CFR citations). The knowledge graph captures the hierarchical structure of the regulations, starting from the general provisions Device_Classification_Panel & descending into more specific device categories & individual devices within each category. The class Manufacturer & Device indicate the query sponsor can request to identify the classification (Class I, II, & III) of the device & requirement for pre-market notification 510(K) or approval (see Figure 2.) based on the Subpart_A_General_Provision, Subpart_B_Diagnostic_Device, Subpart_C_Monitoring_Device, Subpart_D_Prosthetic_Device, Subpart_E_Surgical_Device, and Subpart_F_Therapeutic_Device.

The knowledge graph provides a comprehensive & structured representation of the regulatory landscape for different medical devices, facilitating navigation, compliance assessment, & understanding of the regulatory requirements set forth by the FDA. Additionally, The design facilitates reasoning by utilizing SPARQL commands. This approach involves connecting individual entities & rules at the most granular subsection of the CFR document hierarchy. The knowledge graph was developed using OWL within the open-source Protégé tool [31]. This methodology ensures efficient navigation & comprehension of the regulatory landscape outlined in the CFR document while enabling sophisticated querying

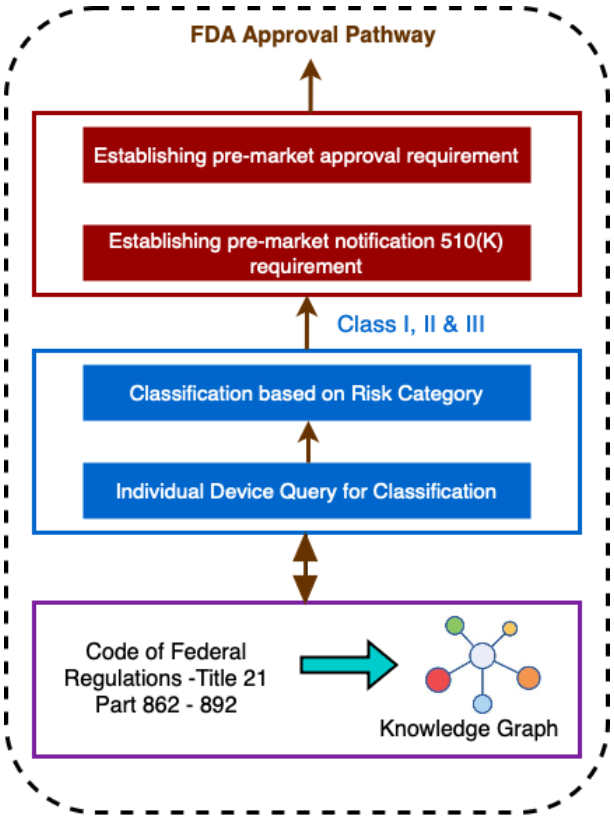


Figure 2. Overview of the proposed semantically rich KG based architecture for automating medical device regulations.

& inference capabilities.

### B. Population of Knowledge Graph

Title 21 of the CFR encompasses Parts 862-892, which consist of numerous sections, subsections, & sentences containing factual information & regulatory rules. We extracted the instances for our ontology from Title 21 of the CFR & added them to the ontology in the respective classes using Protégé. Similarly, we added the data & object properties of the instances using Protégé from Title 21 of the CFR. Below are some of the key example statements from the policies that were considered during the graph population.

- Sec. 870.4280 Cardiopulmonary prebypass filter. [32]
  **Identification:** *A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.*
  ***Classification: Class II*** *(special controls).*
  *The device is* ***exempt*** *from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.*
- Sec. 870.2850 Extravascular blood pressure transducer. [33]
  ***Identification:*** *An extravascular blood pressure transducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to the electrical or mechanical changes produced in the transducer.*
  ***Classification:*** *Class II (performance standards).*

## IV. Experimental Validation

We have validated the design of our KG by having it reviewed by our domain expert collaborator. In addition, we identified use cases from the medical device regulation domain to validate the reasoning component of our framework.

### A. Use case

We describe two use cases of our system in the following subsections. Several other similar use cases exist based on the device's usage.

*1) Case 1:* When the FDA receives a new device approval request from a manufacturer, the first step is to identify its classification level based on the broad descriptions provided in the request since the classification levels determine the next action steps in the regulatory process. The following SPARQL query illustrates how our framework will facilitate the reasoning of such a scenario.

```
PREFIX rdf: <http://www.w3.org/1999/02/22-rdf-
    ↪ syntax-ns#>
PREFIX owl: <http://www.w3.org/2002/07/owl#>
PREFIX rdfs: <http://www.w3.org/2000/01/rdf-
    ↪ schema#>
PREFIX xsd: <http://www.w3.org/2001/XMLSchema#
    ↪ >
PREFIX fdadc: <http://www.semanticweb.org/
    ↪ medicalresearch/FDADeviceClassification#
    ↪ >

SELECT DISTINCT ?device ?description ?
    ↪ classification
WHERE {
  ?device rdf:type fdadc:Device .
  ?device fdadc:Device_Description ?description
      ↪  .

  {
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartA ?
        ↪ subpart .
  } UNION {
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartB ?
        ↪ subpart .
  } UNION {
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartC ?
        ↪ subpart .
  } UNION {
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartD ?
        ↪ subpart .
  } UNION {
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartE ?
        ↪ subpart .
  } UNION {
```

```
    ?device fdadc:ControlledBy/fdadc:
        ↪ ClassifiesDevice/fdadc:hasSubpartF ?
        ↪ subpart .
  }

  ?subpart fdadc:Section_Name ?sectionName ;
         fdadc:Classification ?classification .

   FILTER(STR(?description) = STR(?sectionName)
       ↪ )
}
```

The SPARQL query gives the following result as shown in Figure 3.

| device | description | classification |
|---|---|---|
| D2 | "Biopotential amplifier and signal conditioner" | "Class II (performance standards)" |
| D3 | "Vascular clip" | "Class II (performance standards)" |
| D5 | "Endomyocardial biopsy device" | "Class II (performance standards)" |

Figure 3. SPARQL query results showing the device classification.

*2) Case 2:* When the FDA receives a Balloon Repair Kit device request from a manufacturer, which is a device used to repair or replace the balloon of a balloon catheter, it runs the following SPARQL to determine if premarket approval is necessary & the device's classification. The following SPARQL query illustrates how our framework will facilitate the reasoning of such a scenario.

```
PREFIX rdf: <http://www.w3.org/1999/02/22-rdf-
    ↪ syntax-ns#>
PREFIX owl: <http://www.w3.org/2002/07/owl#>
PREFIX rdfs: <http://www.w3.org/2000/01/rdf-
    ↪ schema#>
PREFIX xsd: <http://www.w3.org/2001/XMLSchema#
    ↪ >
PREFIX fdadc: <http://www.semanticweb.org/
    ↪ medicalresearch/FDADeviceClassification#
    ↪ >

SELECT DISTINCT ?device ?description ?
    ↪ classification
WHERE {
  ?device rdf:type fdadc:Device .
  ?device fdadc:Device_Description ?description
      ↪  .

  ?device fdadc:ControlledBy/fdadc:
      ↪ ClassifiesDevice/fdadc:hasSubpartB ?
      ↪ subpart .

  ?subpart fdadc:Section_Name ?sectionName ;
         fdadc:Classification ?classification .

  FILTER(STR(?description) = STR(?sectionName))
}
```

The SPARQL query gives the following result as shown in Figure 4.

| device | description | classification |
|---|---|---|
| D6 | "Catheter balloon repair kit" | "Class III (premarket approval)" |

Figure 4. SPARQL query results showing the device classification and premarket approval requirement.

## V. Discussion

The risk categorization for medical devices is based on the 1,700 distinct types of devices within the CFR Title-21. These regulations governing medical devices are presently presented in extensive textual formats, often containing cross-references to other documents. Consequently, comprehending these regulations requires considerable effort to parse through & understand. Consequently, device manufacturers face substantial costs during the regulatory process as they strive to comply with the myriad rules & policies mandated by the FDA. In this paper, we have developed novel semantically rich compliance KGs to automate the 1,700 distinct types of devices within the CFR Title-21, which are arranged into 16 medical specialty "panels." The proposed framework is validated using the SPARQL query as detailed in section IV-A. The primary step for the FDA is to classify the device based on the risk into Class I, II, & III as detailed in Table I. In the section 3, the request for classification of a new device into classes is given. Our framework, successfully facilitate the reasoning of such a scenario, the SPARQL query outputs as the device class as 'Class II' as given in Figure 3. The Class III devices present notably higher risks to patients, the most stringent process mandated by the FDA for devices. PMA entails the submission of clinical evidence to substantiate their application. Furthermore, Class III devices are essential for supporting or maintaining human life, preventing deterioration of human health, or posing a potentially unreasonable risk of illness or injury. In section IV-A2, the new device classification request & if the PMA requirement is necessitated as per the CFR Title-21. In Figure 4. the output of the SPARQL query is outlined as 'Class III (premarket approval)' required.

The AI-based models are rapidly seeking clearance & are often used for disease diagnostic purposes. The device is regulated by CDRH at FDA. It was reported that 108 & 139 AI/ML-based medical device were approved in 2023 & 2022 alone, which accounts for 35% of all of the medical device approved to date [34]. The approval process is cumbersome & the time for approval may increase depending on the FDA workload. Our proposed framework can ease the effort to provide rules & policies for Medical devices & translate the CFR rule into a machine-processable format that can be reasoned over.

## VI. Conclusion and Future Work

Regulatory documents for medical devices, such as CFR - Title 21, are currently managed as large text documents & require significant human effort to analyze due to their lengthy & intricate nature which is time-consuming & costly. This paper details our novel framework leveraging AI/knowledge representation & Semantic Web to automate pre-market processes reliant on FDA medical device policies / CFR 21 knowledge. Our framework classifies devices based on risk categories & requirements for 510(K) notification or pre-market approval. The validation effort for this paper focuses on analyzing CFR Title 21 Part 870, specifically "*Subpart B* -

*Cardiovascular Diagnostic Devices.*" The overarching objective of this research is to develop an efficient & automated Question and Answer (QnA) system that can be used by manufacturers & regulators to significantly reduce the human effort & cost in medical device regulation.

As part of our ongoing work, we are populating all the 1700 approved devices into our KG. We are also collaborating with other domain experts to validate & enhance our KG design. We are also using advanced text analytics approaches to further refine the data populated into our framework.

## VII. Acknowledgement

We thank Dr. Andrea Iorga for helping in the expert validation of the design of our KG. This research was partially supported by the NSF award 2310844, IUCRC Phase II UMBC: Center for Accelerated Real time Analytics (CARTA).

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