

# In-Depth Analysis of Recall Initiators of Medical Devices with a Machine Learning-Natural Language Processing Tool

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**Keywords:** Recall Initiator Analysis, Medical Device, Artificial Intelligence, Supply Chain Risk Management, Reverse Logistics.


**Abstract:** Persistent quality problems with medical devices and the associated recall present potential health risks to patients and users, bringing extra costs to manufacturers and disturbances to the entire supply chain (SC). Recall initiator identification and assessment are the preliminary steps to prevent medical device recall. Conventional analysis tools are inappropriate for processing massive and multi-formatted data comprehensively to meet the higher expectations of delicacy management with the increasing overall data volume and textual data format. To address these problems, this study presents a big data analytics-based Machine learning (ML) – Natural language Processing (NLP) tool to identify, assess and analyse the medical device recall initiators based on the FDA ‘Medical Device Recalls’ database from 2018 to 2024, inclusive. Results suggest that the Density-Based Spatial Clustering of Applications with Noise (DBSCAN) clustering algorithm can present each single recall initiator in a specific manner, therefore helping practitioners to identify the recall reasons, comprehensively. This is followed by text similarity-based textual classification to assist practitioners in controlling the group size of recall initiators and provide managerial insights from the operational to the tactical and strategic levels. More proactive practices to prevent medical device recalls are expected in the future.


## 1 INTRODUCTION

Medical devices play an increasingly significant role in healthcare delivery (Thirumalai & Sinha, 2011) which is especially witnessed after the global pandemic. The medical device industry has grown remarkably in revenue and technological sophistication (Sarkissian, 2018). However, several hundred medical device recalls occur each year (Gagliardi et al., 2017). In 2022, the U.S. Food and Drug Administration (FDA) reported 70 highest-risk recalls, compared to an average of 47 over the previous five years (Taylor, 2023). Serious medical device adverse events have overtaken industry growth by 8% and recalls have increased on par with the growth rate (Sarkissian, 2018). Persistent quality problems with medical devices and the associated recalls will not only present potential health risks to patients and personnel users of these devices

(Mukherjee & Sinha, 2018; Thirumalai & Sinha, 2011) but also result in high extra costs to the manufacturer, its supply chain members (Ahsan & Gunawan, 2014; Morgenthaler et al., 2022) and the healthcare system (Ghobadi et al., 2019). Besides the huge litigation fees incurred, the recall event can result in estimated losses of billions of dollars in lost sales (Marucheck et al., 2011) as current and potential clients will turn to other competitors because of lost reputation (Blom & Niemann, 2022). Although medical devices have become an indispensable component (often lifesaving) in health care delivery, sometimes they also become sources of significant risk to the consumers of medical devices (Thirumalai & Sinha, 2011).

Recalls are reverse logistics where recalled products, information, and cash flow are in the opposite direction of the normal supply chain. The process of product recall is cumbersome and

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members of the entire supply chain are directly or indirectly affected by recalls (Ahsan & Gunawan, 2014).

A medical device recall is a voluntary action by manufacturers to remove or correct devices that violate the National Food and Drug Administration (e.g. FDA in the U.S, EMA in the EU or Health Canada in the CA) regulations. These corrections are often related to manufacturing defects, functional defects (Thirumalai & Sinha, 2011), software failure (Bliznakov, Mitalas, & Pallikarakis, 2007; Fu et al., 2017; Wallace & Kuhn, 2001), device design, process control, deceptive presentations and labelling (Sarkissian, 2018).

The FDA classifies medical devices according to the risk degree of health threat to users, from low (Class I) to middle (Class II) high (Class III). Class I devices are deemed to pose the least amount of risk to patients since their designs are straightforward, they are easy to produce, and they do not pose any danger to patients, while Class III devices are of substantial importance in human health (Sarkissian, 2018) and require a premarket approval application (PMA) (FDA, 2024a). The recall classification is the reverse of the medical device classification logic whereby class III recalls only reflect regulatory violations with minimal or no health risks, Class I recalls denote situations in which exposure to a product will cause serious adverse health consequences or death (Sarkissian, 2018). For a Class I recall, the company will notify the customers and issue a press release to notify the public (Villarraga, Guerin, & Lam, 2007).

Medical device recalls are not uncommon, and the safety of medical devices may pose public health risks (Gagliardi et al., 2017). Recall initiator identification, assessment, and analysis are used to overcome and prepare for a possible medical product recall (Ahsan & Gunawan, 2014). Recall risk factor identification and assessment are the preliminary steps to prevent medical device recalls. Controlling medical device recall operations and identifying high-risk products to strengthen anticipatory risk control action can improve the quality of consumer use and reduce recall operations.

Realising the importance of medical device recalls (Ahsan & Gunawan, 2014; Gagliardi et al., 2017; Villarraga et al., 2007), researchers analysed medical recall initiators with historical recall data from different time periods to provide insights into recall trends (Ahsan & Gunawan, 2014; Gagliardi et al., 2017; Sarkissian, 2018) with commonly used data analysis tools. However, with the increasing data volume and widely used textual data, conventional analysis tools are not appropriate for processing

massive and multi-formatted data comprehensively and completely to meet the higher expectations of dealing with efficiency and delicacy management.

To address the shortcomings in dealing with the efficiency and data process versatility of conventional tools in the practical context of big data volume and multi data format, this study presents a Machine Learning– Natural Language Processing work tool based on big data analytics that remained unexplored by previous studies to identify and analyse the medical device recall initiators in a comprehensive and complete manner and to present up-to-date information concerning medical device recalls according to the publicly available FDA medical device recall database from 2018 to 2024 inclusive.

This information contributes to the literature on the risk identification and assessment of the medical device supply chain. It is also relevant to policymakers, health system leaders, clinicians, and regulators who want to understand the possible public health risks posed by medical devices and explore whether current approaches to post-market surveillance of medical devices are appropriate.

This research also contributes a new analytical tool for the supply chain risk analysis research community to achieve efficiency, reliability, and thoroughness in risk identification and assessment. From the digital technology implementation perspective, this research manages to expand the application scenarios of AI to the reverse side of the medical device supply chain which is neglected by previous studies (Hu & Ghadimi, 2023).

The paper is organized as follows: Section 2 discusses a literature review of the medical device recall analysis and previous relevant research. Section 3 describes the data collection and research methodology process. This is followed by results and discussion presented in Section 4. Finally, the research summary and future research directions are highlighted in Section 5.

## 2 LITERATURE REVIEW

Table 1 illustrates previous research on medical device recall analysis categorized by recall product category, recall initiator category, data analysis tool, analysis period, and data source.

The previous analysis investigated partly either recall device category or recall initiators. Gagliardi et al. (2017) performed a comprehensive analysis that went through all types of devices and recall initiators in the Canadian region wide. However, the

Table 1: Literature Categorization.

Ref.	Device	Recall Initiator	Analysis Tool	Period	Data
(Wallace & Kuhn, 2001)	Anesthesiology, cardiology, diagnostics, radiology, general hospital use, and surgery categories	Software failure	Conventional	1983-1997	FDA
(Bliznakov et al., 2007)	Device class I-III	Software failure	Conventional	1999-2005	FDA
(Villaraga et al., 2007)	Device class I-III	Recall class I	Conventional	2004-2006	FDA
(Yi, Shenglin, Qiang, & Hanxi, 2013)	Device class III	Recall class I-III	Conventional	2005-2006	FDA, US.
(Somborg, McEwen, & Molnar, 2014)	Cardiovascular and Noncardiovascular category	Recall class I-III	Conventional	2005-2012	FDA
(Connor et al., 2017)	Radiation Oncology Category	Recall class I-III	Conventional	2002-2015	FDA
(Gagliardi et al., 2017)	Device class I-IV	Recall Class I-III	Conventional	2005-2015	Health Canada,
(Sarkissian, 2018)	Device class III	Recall Class I	Conventional	2014-2018	FDA.
(Vajapay & Li, 2020)	Orthopaedics category	Recall class I-II	Conventional (Excel)	2015-2019	FDA
Present study	Device class I-III	Recall class I-III	Big Data and AI	2018-2024	FDA

comprehensive analysis based on other geographical spaces is limited. The previous analyses do not reveal the root causes of medical device recalls, which is critical to help manufacturers understand the failures and prevent recalls in the future (Fu et al., 2017). Moreover, the analytic tools leveraged by previous

studies are conventional tools such as Excel (Vajapay & Li, 2020). However, with the increasing data volume, and widely used textual data, conventional analysis tools are not appropriate for processing massive, multi-formatted data and meeting the higher expectations of dealing with efficiency (Sagiroglu & Sinanc, 2013) and delicacy management. Lastly, this study provides an up-to-date medical device recall analysis.

To address these gaps, this research proposed a Machine Learning – Natural Language work tool based on big data analytics that remained unexplored by previous studies to identify and analyse the medical device recall initiators, presenting up-to-date information concerning medical device recalls according to the public medical device recall database from 2018 to 2024. This research explores a new attempt at medical device recall initiator analysis from a methodology perspective. This research attempts to overcome the shortcomings in dealing with efficiency and data process versatility of conventional tools in the practical context of big data volume and multi data format with AI tools.

### 3 DATA COLLECTION AND RESEARCH METHODOLOGY

#### 3.1 Data Collection

Data is scraped from the FDA open database of medical device recall using API calls (FDA, 2024c). The FDA database only allowed 1000 records to be retrieved at once, the maximum loop tested successfully by the current computer device is 7. Therefore, 7000 rows of data records were included in the final version dataset used for data analysis of this research, dated from January 1, 2018, to April 15, 2024. This research organized an information profile for analysis that includes contents: 1) product code, 2) recall posted date, 3) recalling firm, 4) root cause description, 5) product quantity, 6) device name and 7) device class by using two API addresses.

Columns 1-5 were extracted from URL= <https://api.fda.gov/device/recall.json> while URL= <https://api.fda.gov/device/classification.json> is the source of columns 6-7. These two separate datasets can be merged and tailored to the one that meets the requirements for this research as they share the same 'product\_code' column. The merged dataset for recall initiators analysis in this research is briefly illustrated in Table 2.

Table 2: The example of merged recall dataset.

PC	RPD	RF	RCD	PQ	DN	DC
JWH	01/10/2018	Smith &Nep hew, Inc.	Other	10792 units	Knee	2

Column names are abbreviated to keep a suitable table size in this article. While ‘PC’ represents ‘product code’, ‘RPD’ is ‘Recall Posted Date’, ‘RF’ is ‘Recalling Firm’, ‘RCD’ is ‘Root Cause Description’, ‘PQ’ is ‘product quantity’, ‘DN’ is ‘Device Name’, and ‘DC’ is ‘Device Class’.

It can be found that the root cause description contains human-written and unstructured (Fu et al., 2017) short text determining the general type of recall cause, by the FDA (FDA, 2024b) such as ‘Process design’, ‘Nonconforming Material/Component’, ‘Under Investigation by firm’, ‘Device design’, ‘Employee error’, ‘Process control’ and ‘Other’. This research considers the contents in the ‘root\_cause\_description’ column as the recall initiators. With the unstructured short text data, some classic analysis methods are not applicable. Machine learning is a capable tool for dealing with massive data with both numerical and short textual format (Sun, 2019).

Before implementing the machine learning approach, the merged dataset was cleaned by removing all special characters, null values, duplicated data, outliers, and any other content that does not add value to the analytics results. All the analysis work was performed on the Google Colab platform using Python 3.10.

### 3.2 Research Method

ML is defined as “the field of study interested in the development of computer algorithms to transform data into intelligent actions” (Sheridan et al., 2020). ML has been used in medical device-related research to identify and discover trends and patterns of uncertain demand (Xu & Chan, 2019) to improve process (Kovačević, Gurbeta Pokvić, Spahić, & Badnjević, 2020; Raschka & Mirjalili, 2019; Xu & Chan, 2019). ML algorithms can be categorized into three groups: supervised learning, unsupervised learning, and reinforcement learning (Raschka, 2015). The unsupervised learning techniques such as clustering can be used to discover hidden structures or patterns, grouping the separated data based on their similarities for the unstructured input short text data in the ‘root cause description’ column of this research. Clustering is the appropriate machine

learning technique for this research as it provides a means for identifying trends and patterns that may not be obvious.

The Density-Based Spatial Clustering of Applications with Noise (DBSCAN) algorithm was leveraged to identify the recall initiators in this research. In the face of 7000 or more records of recall initiators in this research, pointing out the cluster numbers in advance is difficult, classical clustering methods, such as Spectral Clustering and K-means clustering (Murugesan, Cho, & Tortora, 2021) require users to select the number of clusters first, often arbitrarily, while the DBSCAN does not require users to select the number of clusters. Moreover, the DBSCAN can be used with both numerical data and short text data used for recording the recall initiators and is suitable for identifying outliers (Sheridan et al., 2020). It requires the choice of two user-defined parameters, the neighbourhood distance epsilon ( $\epsilon$ ) and the minimum number of points (minPts) (Çelik, Dadaşer-Çelik, & Dokuz, 2011) or so-called MinSamples (Murugesan et al., 2021). The number of clusters is generated as a product of the analysis, and instances in low-density regions are tagged as outliers rather than assigned to a cluster. A cluster forms when there is at least a minPts within a user-specified threshold  $\epsilon$  of a given point.

The small  $\epsilon$  values often result in large numbers but small sizes of clusters (Sheridan et al., 2020). The minPts represents the minimum number of points required to form a cluster, smaller minPts generally results in a large number of clusters (Creţulescu, Morariu, Breazu, & Volovici, 2019) but the small size of each cluster. The small  $\epsilon$  and small minPts can be helpful in this research to detect the recall initiators completely with the least overlap. To find the  $\epsilon$ , we vary the  $\epsilon$  between 0.1 and 0.9 and keep the minPts constant for the 7000 records.

Table 3: Cluster numbers with different  $\epsilon$ .

$\epsilon$	minPts	No. of Clusters
0.1	5	36
0.2	5	36
0.3	5	36
0.4	5	36
0.5	5	36
0.6	5	35
0.7	5	33
0.8	5	29
0.9	5	26

This research setting  $\epsilon = 0.1$  to find the maximum clusters based on the results in Table 3 and the optimal results from Murugesan et al. (2021). We tested the scenarios where  $\text{minPts} = [1,10]$ . The cluster number results remain at 36 from  $\text{minPts} = 4$ . Therefore, the decision on parameters is that  $\epsilon = 0.1$ ,  $\text{minPts} = 4$ .

#### 4 RESULTS AND DISCUSSION

Table 4 illustrates the results of recall initiator identification obtained by implementing the DBSCAN algorithm.

Table 4: Recall initiators identified by the DBSCAN clustering.

Cluster	Recall initiator	Case Number
0	Other	197
1	No Marketing Application	45
2	Under Investigation by firm	1699
3	Software design	270
4	Radiation Control for Health and Safety Act	43
5	Material/Component Contamination	42
6	Device Design	1046
7	Employee error	94
8	Process control	1030
9	Process change control	125
10	Error in labelling	98
11	Software Manufacturing/Software Deployment	13
12	Component design/selection	131
13	Software Design Change	45
14	Labelling Change Control	81
15	Labelling design	108
16	Process design	135
17	Incorrect or no expiration date	23
18	Software change control	16
19	Mixed-up of materials/components	29
20	Component change control	116
21	Unknown/Undetermined by firm	165
22	Nonconforming Material/Component	643
23	Packaging	49

24	Labelling mix-ups	34
25	Packaging process control	135
26	Vendor change control	99
27	Storage	134
28	Equipment maintenance	72
29	Pending	51
30	Software design (manufacturing process)	13
31	Use error	33
32	Packaging change control	49
33	Package design/selection	18
34	Labelling False and Misleading	14
35	Environmental control	96

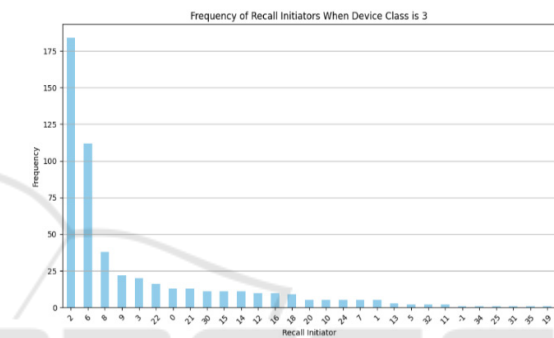


Figure 1: Frequency of Recall Initiators for Class III Device.

36 recall initiators are listed in Table 4 after the DBSCAN clustering. The most important reason for the medical device recall of the 7000 records is ‘Under investigation by firm’, accounting for 24.3 % of all the recall cases. This was followed by the ‘Device design’ reason that resulted in 1046 cases of medical device recall. ‘Process control’ is also an important recall initiator and ranked third place among all recall initiators. The DBSCAN clustering can present each single recall initiator in a specific manner and help practitioners comprehensively identify the recall reasons. Results based on the device class can also be presented. Fig. 1 illustrates that the most frequent recall cause for the high-risk class III devices is ‘Under investigation by firm’.

It can be noticed in Table 4 that some listed recall initiators can be aggregated and displayed under the same label (Sarkissian, 2018). For instance, cluster 3 ‘Software design’, cluster 11 ‘Software Manufacturing/Software Deployment’, cluster 13 ‘Software Design Change’, cluster 18 ‘Software change control’ and cluster 31 ‘Software design (manufacturing process)’ can be aggregated in a same ‘Software’ label (Connor et al., 2017). Similar situations, such as cluster 8,9,16 can be aggregated in

a ‘Process’ label, cluster 14,15,24, and 34 can be aggregated in a ‘Labelling’ label (Sarkissian, 2018).

The entire list of 36 exact recall initiators retrieved by the DBSCAN algorithm is helpful for practitioners at the operational level. At the same time, the aggregated label can release the burden of investigating every specific detail for the practitioners at the tactical and strategic levels. In this case, to make the results of the recall initiator identification more widely acceptable, this research presents a textual classification step to aggregate the label based on the text similarity after the DBSCAN clustering. This is a new attempt to aggregate recall reasons using NLP techniques, compared to previous studies (Sarkissian, 2018) that rely on manual observation and experience (Connor et al., 2017). The NLP techniques can help reduce manual work and efficiently perform in large datasets.

This research leveraged the text similarity measure for cluster aggregate with the first 10 letters of each recall reason phrase (Kenter & De Rijke, 2015). The results of combining groups by text similarity are presented in Table 5.

Table 5: Results of recall initiators clustering after textual classification.

Cluster	Recall initiator	Case Number
1	['Component change control', 'Component design/selection']	247
2	['Device Design']	1046
3	['Employee error']	94
4	['Environmental control']	96
5	['Equipment maintenance']	72
6	['Error in labelling']	98
7	['Incorrect or no expiration date']	23
8	['Labelling Change Control', 'Labelling design', 'Labelling False and Misleading', 'Labelling mix-ups']	237
9	['Material/Component Contamination']	42
10	['Mixed-up of materials/components']	29
11	['No Marketing Application']	45

12	['Nonconforming Material/Component']	643
13	['Other']	197
14	['Package design/selection', 'Process design']	153
15	['Packaging', 'Packaging change control', 'Packaging process control']	233
16	['Pending']	51
17	['Process change control', 'Process control']	1155
18	['Radiation Control for Health and Safety Act']	43
19	['Software design']	270
20	['Software change control', 'Software design (manufacturing process)', 'Software Design Change', 'Software Manufacturing/Software Deployment']	87
21	['Storage']	134
22	['Under Investigation by firm']	1699
23	['Unknown/Undetermined by firm']	165
24	['Use error']	33
25	['Vendor change control']	99

Results in Table 5 indicate that the number of clusters decreased to 25 from 36 after the labelling of the group aggregate. The textual classification step after the DBSCAN clustering can assist users in controlling the group size of recall initiators to gain insights beyond the operational level.

To highlight the utilisation of the proposed ML-NLP tool, a comparison of recall initiators of class II devices is presented in Table 6, referring to the results from Connor et al. (2017) with conventional tools.

The comparison of the results in Table 6 shows that the high-risk factors of medical device recall were identified differently after the textual classification. If the users determine the prior recall initiators based on the results from conventional analysis, it might be misleading in some circumstances. For example, ‘Software’ is recognised as the second important recall initiator of class II device. However, after the ML-NLP process, it has been found that the ‘Process control’ problem should be the second priority and medical device

manufacturers need to place enough resources to address it for fewer recall events with better performance. This ML-NLP work tool can not only capture specific details of each recall initiator but also interpret the inner connection of each existing initiator that is recorded manually and finally present a reasonable result that is closer to practice for users.

Table 6: Comparison of top 10 recall initiators of class II.

Top 10 Recall reasons illustrated by Connor et al. (2017)	Top 10 Recall reasons after present ML-NLP tool
Other/Under investigation	['Under Investigation by firm']
Software	['Process change control', 'Process control']
Material/Component	['Device Design']
Device design/change control	['Nonconforming Material/Component']
Process	['Software design']
Labelling	['Other']
Packaging	['Component change control', 'Component design/selection']
Component	['Package design/selection', 'Process design']
Employee/use error	['Unknown/Undetermined by firm']
Radiation control for Health and Safety Act	['Vendor change control']

Besides replicating the functions and outcomes that conventional analysis tools presented in previous studies. This AI-supported tool can identify critical features of medical device recalls from unstructured text, a task that typically requires more manual effort with traditional tools illustrated in Tables 5 and 6. The implemented ML-NLP tool captures features in a more automated, intelligent, and efficient manner, with fewer data format limitations than conventional analysis methods. The advantages in data processing versatility and efficiency become prominent as the data volume increases. The faster processing speed enables medical manufacturers to quickly identify and assess recall initiators, ultimately leading to faster implementation of risk prevention measures. This can help reduce public health risks and lower additional costs for the entire medical device system.

## 5 CONCLUSIONS

Previous medical device initiator analysis studies neglect big data analytics and AI. This led to the root causes of medical device recalls not being revealed wholly and comprehensively. However, being able to identify the root causes of the failures in depth is critical to help manufacturers understand the failures and prevent recalls in the future (Fu et al., 2017).

This research contributed an ML-NLP work tool based on big data analytics techniques to identify, assess, and analyse medical device recall initiators. With comprehensive, practical, and reasonable considerations, this research presented up-to-date information concerning medical device recalls.

The ML-NLP work tool proposed by this research can be leveraged as a scalable solution for general scenarios in the domain of risk identification and risk assessment on both the forward and reverse sides of the supply chain. This research contributes a new risk analysis tool for the supply chain risk management community.

Further research can be (1) applying this ML-NLP risk analysis tool to other industry domains and on the forward side of the supply chain and (2) implementing synonym analysis in this ML-NLP tool. In natural language, the authors use various expressions to express the same opinions (Sun, 2019). For example, 'Under Investigation by firm' and 'Unknown/Underdetermined by firm' in Table 6 can be recognized in the same cluster by the meaning of natural language with synonym analysis. Methods for automatic determining of DBSCAN parameters (Starczewski, Goetzen, & Er, 2020) can be proposed and embedded in this ML-NLP tool to make it more intelligent and user-friendly.

This research presented descriptive analysis with the ML-NLP tool, predictive study such as forecasting the recall cause of different device can be investigated in the future.

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