

# FDA Regulatory Trends in Artificial Intelligence-Enabled Medical Devices in Radiology: 2015-2025

Woo Sik Kim<sup>1</sup>, Dorene Blum<sup>1</sup>

<sup>1</sup>Des Moines University College of Osteopathic Medicine

## Purpose

Despite increasing use of artificial intelligence (AI)-enabled medical devices in clinical practice, the longitudinal trends in the U.S. Food and Drug Administration (FDA)-approved AI-enabled medical devices have not been well studied.

**This study examines 10-year trends in FDA-approved AI-enabled medical devices with emphasis on radiology devices.**

## Background

AI is rapidly transforming healthcare, with growing integration into diagnostic, prognostic, and workflow applications across multiple specialties.

In recent years, there has been a marked increase in FDA-approved AI-enabled devices, particularly in radiology, involving imaging-related applications such as **image processing, detection, and triage**. Some of these include:

- ❖ Tools that automatically detect critical findings **on chest x-rays** and prioritize them for radiologist review<sup>1</sup>
- ❖ AI-based **stroke imaging tools** (e.g., large vessel occlusion detection platforms) that analyze vascular imaging and enable rapid triaging of emergent cases<sup>2</sup>

Most FDA-approved AI devices in radiology are designed for **assistive functions** such as detection, prioritization, and workflow optimization, rather than fully autonomous diagnosis.<sup>3</sup>

However, **existing literature has primarily focused on technical performance and clinical applications**, with less emphasis on regulatory approval patterns over time.<sup>4</sup>

There is also a **limited understanding of how AI-enabled devices are distributed across regulatory categories and product codes**, which may reflect the scope and focus of emerging technologies within radiology.

## Methodology

AI-enabled medical devices approved between **2015 and 2025** were extracted from a **publicly available FDA dataset**.<sup>5</sup>

- ❖ Inclusion criteria: the use of AI-related terminology in FDA approval summaries and/or device classifications<sup>4</sup>
- ❖ Devices were categorized by radiology or non-radiology specialty and by primary product code
- ❖ Annual growths and frequency distributions were analyzed using R version 4.5.0

*\*According to the FDA, the data may not represent a comprehensive list of every AI-enabled medical device.*

## Results

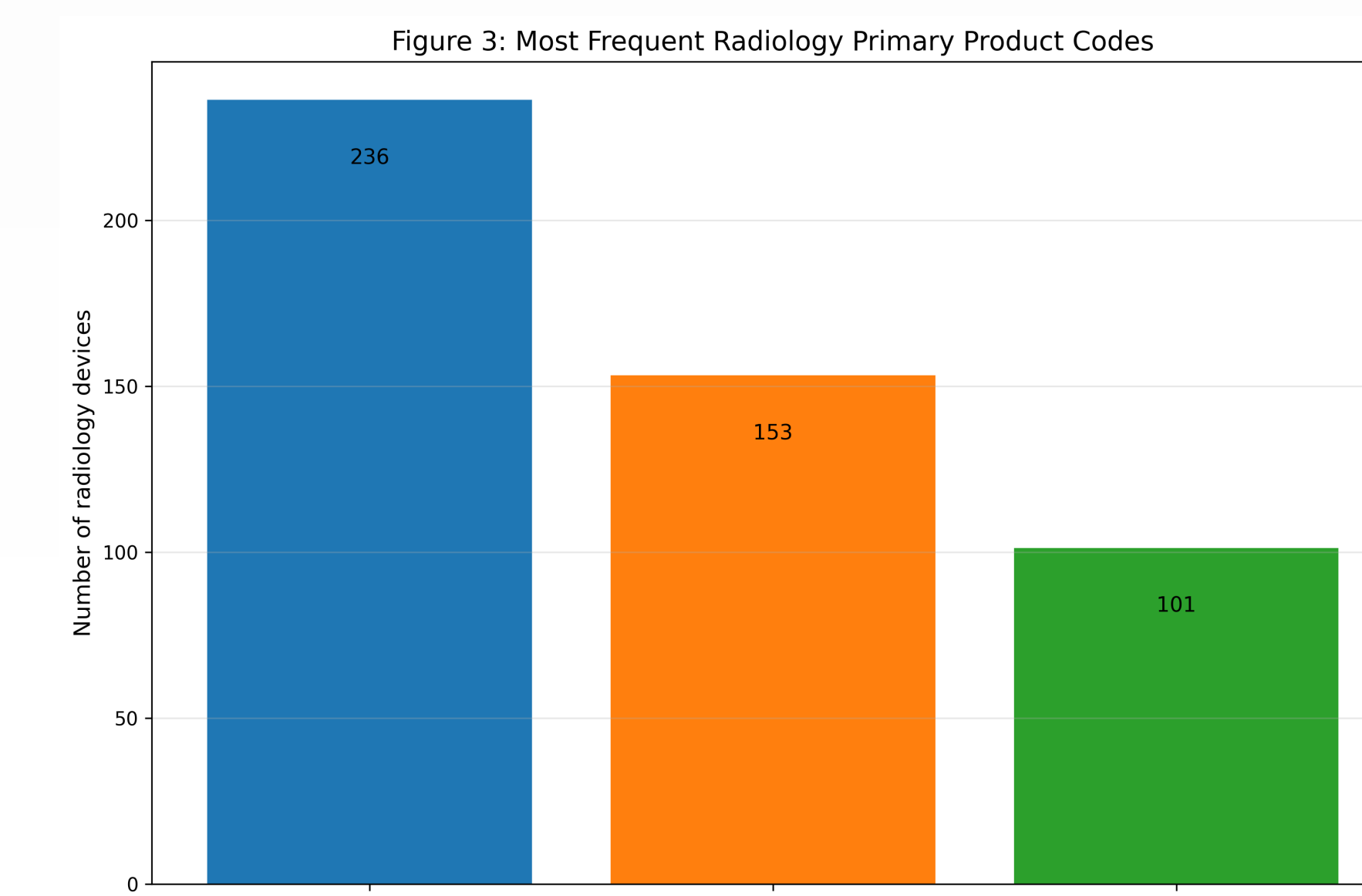
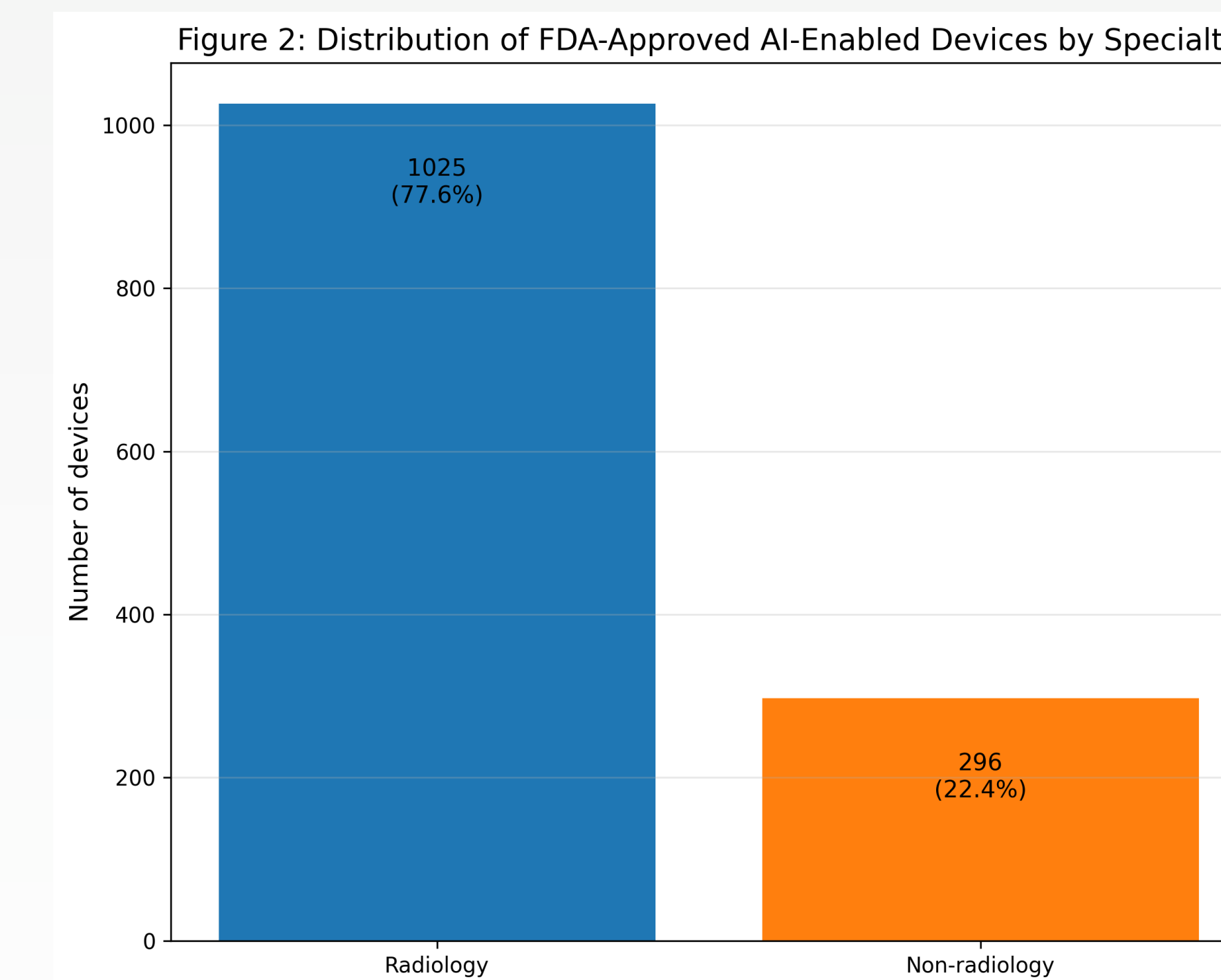
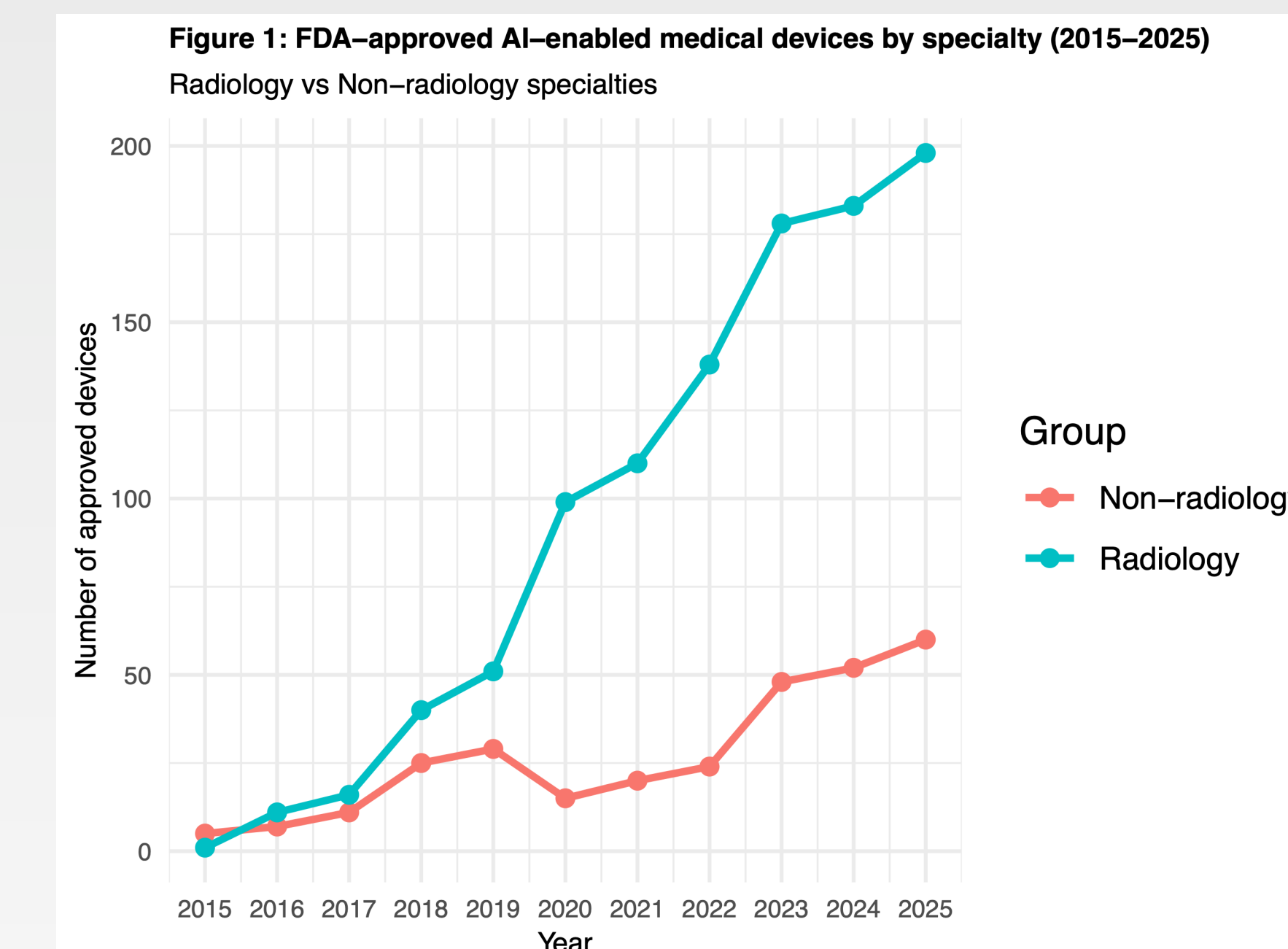
Category	Radiology	Non-Radiology
Total Devices	1,025	296
Percentage of Total	77.6%	22.4%
Annual Average Growth	19.7/year	5.5/year
Unique Product Codes	37	116
Growth Range (2015 → 2025)	1 → 198	5 → 60

Table 1: Distribution and Growth of FDA-Approved AI-Enabled Medical Devices (2015-2025)

Product Code	Description	Number of Devices	Percentage
QIH	Automated radiological image processing software	236	23.0%
LLZ	Radiological image processing systems	153	14.9%
IYN	Ultrasonic pulsed Doppler imaging systems	101	9.85%

Table 2: Most Frequent Radiology Product Codes of FDA-Approved AI-Enabled Medical Devices (2015-2025)

## Graphical Analysis



## Conclusions

Radiology dominates the AI regulatory landscape, accounting for **over three-quarters (77.6%) of all FDA-approved AI-enabled medical devices between 2015-2025**, highlighting its central role in clinical AI development.

AI-enabled device approvals have **grown rapidly over the past decade**, with radiology demonstrating substantially higher absolute growth compared to non-radiology specialties.

Despite this growth, **radiology devices remain concentrated within a limited number of primary product codes**, suggesting a focus on specific application domains such as image processing and workflow support.

These findings **provide important regulatory context for the development of AI in healthcare**, emphasizing both the rapid expansion and the domain-specific concentration of AI-enabled technologies in radiology.

## References

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