2023 510(K) CLEARANCES MID-YEAR REPORT

FOCUSING ON TIME TO CLEARANCE

Presented by Kimimed Ltd.

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INTRODUCTION

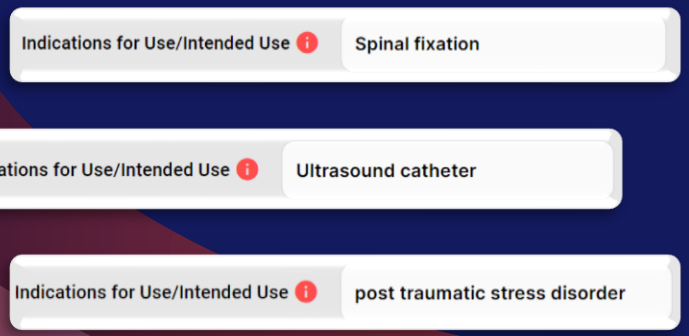
- We examined published data on medical devices cleared by the US Food and Drug Administration (FDA) through the Premarket Notification program, more commonly known as the 510(k).
- The intent of this analysis is to examine how long it takes device manufacturers to get FDA clearance in 2023, look at trends and assess differences between medical specialties.
- Throughout the analysis you will see references to "clearance". Technically, the FDA does not "approve" devices via the 510(k) process – they "clear" them for sale in the US.
- As always, we welcome your feedback on this report!
- Reach out to us for more in-depth analyses, in your domain of interest: info@kimimed.io.

BEFORE WE DIVE IN, A QUICK WORD ABOUT KIMI

Kimi simplifies the process of searching for information across FDA databases. Its AI engine extracts and aggregates critical information hidden within documents and databases, empowering your competitive & regulatory strategy, saving hours of painful searching.

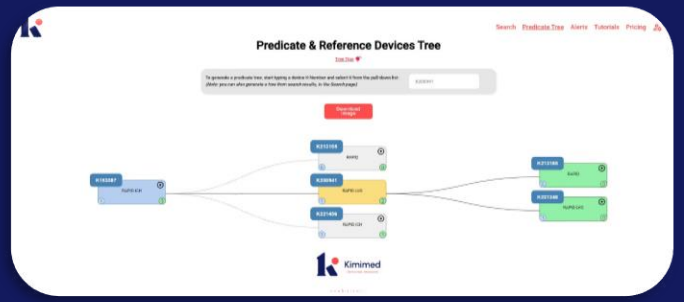
Intuitive search

- Free-text searches using natural language
- Allows to searching using keywords (e.g., indications or technology)
- More flexible searches and more results than possible using the FDA website



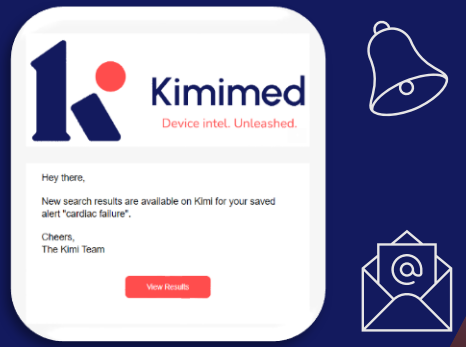
Visual representation

- Automatic Predicate Tree depicting the device lineage
- Helps to easily and quickly identify similar devices/ predicates
- Reduces the risk of missing an important predicate/competitor



Custom notifications

- Customizable email notifications
- Alerting users when new devices that match their criteria of interest are cleared or approved
- For 510(K): Automatic emails when the submission doc gets published



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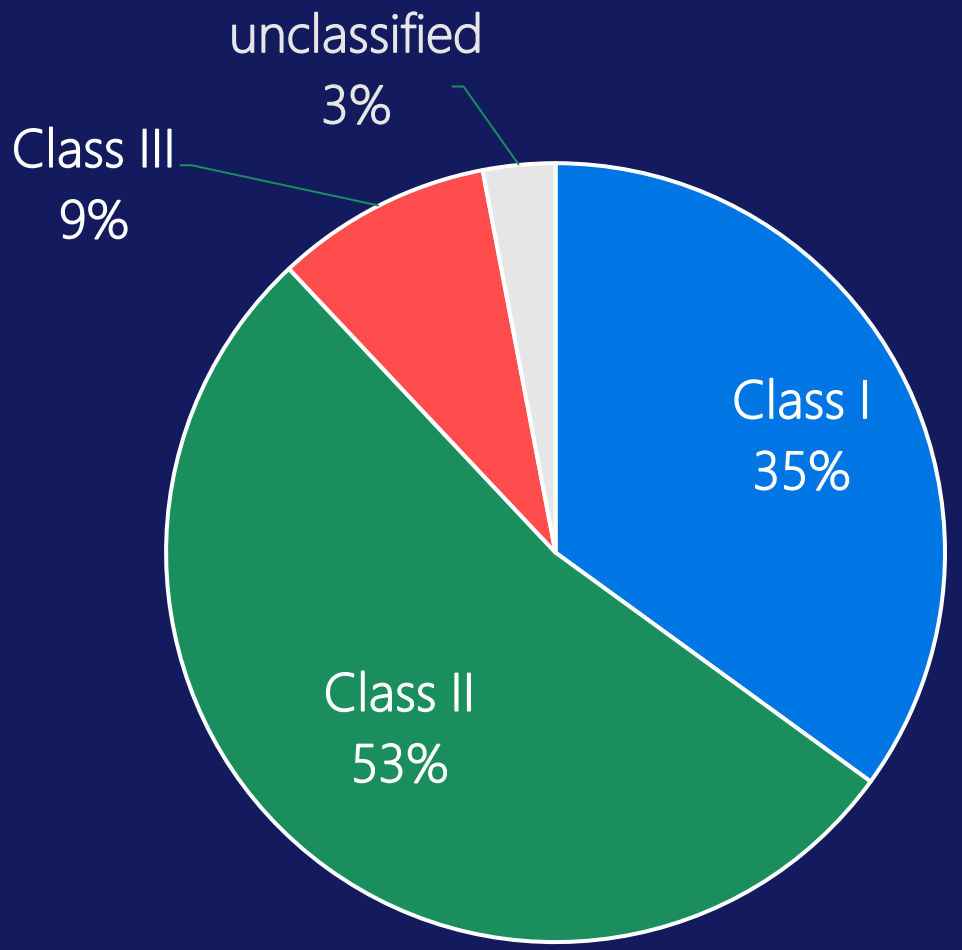
AND NOW, LET'S DIVE IN...

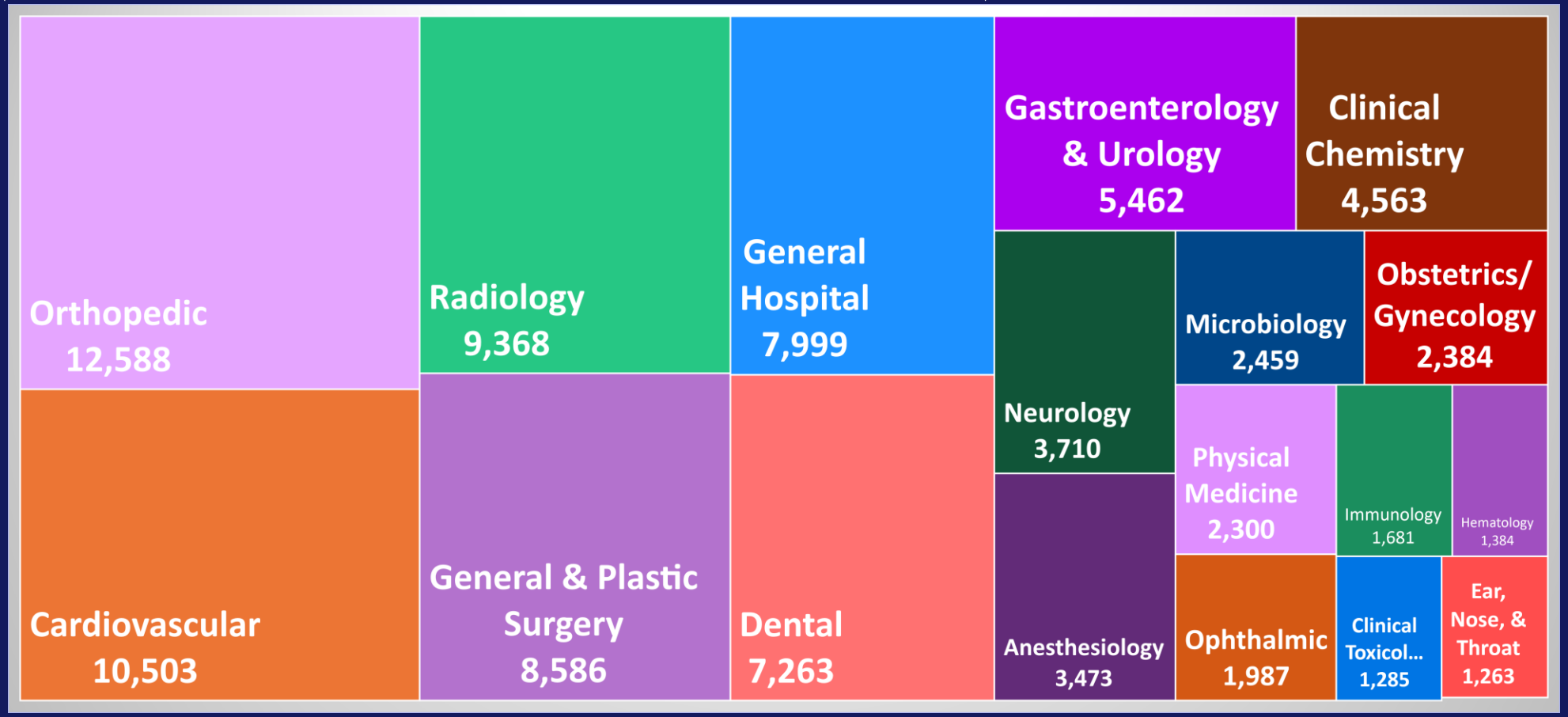
With a bit of context first.

OVERALL DISTRIBUTION OF DEVICES BY FDA REGULATORY CLASS



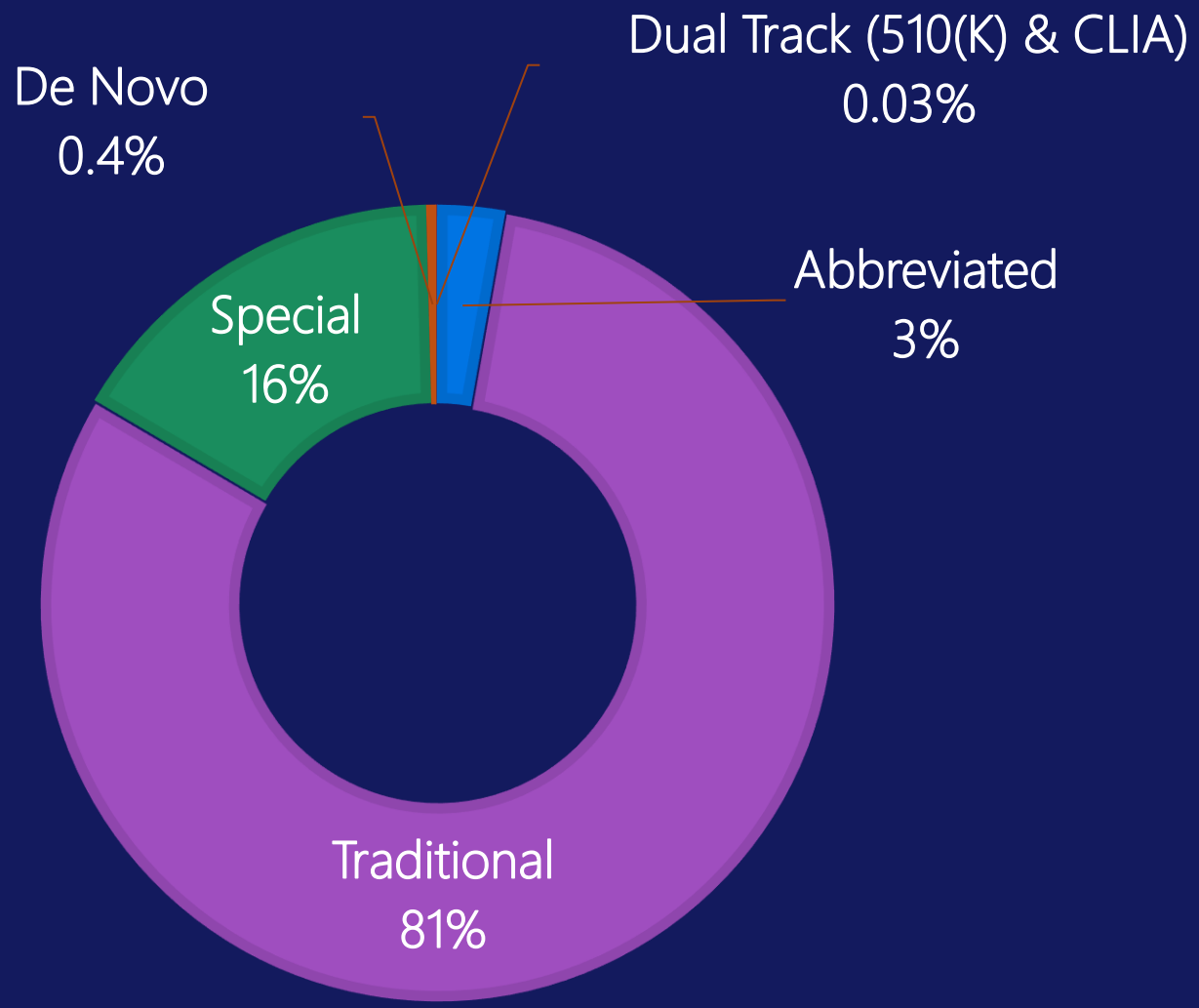
510(K)'S PER MEDICAL SPECIALTY ('96-'23)

>60% of devices fall under 6 medical specialties

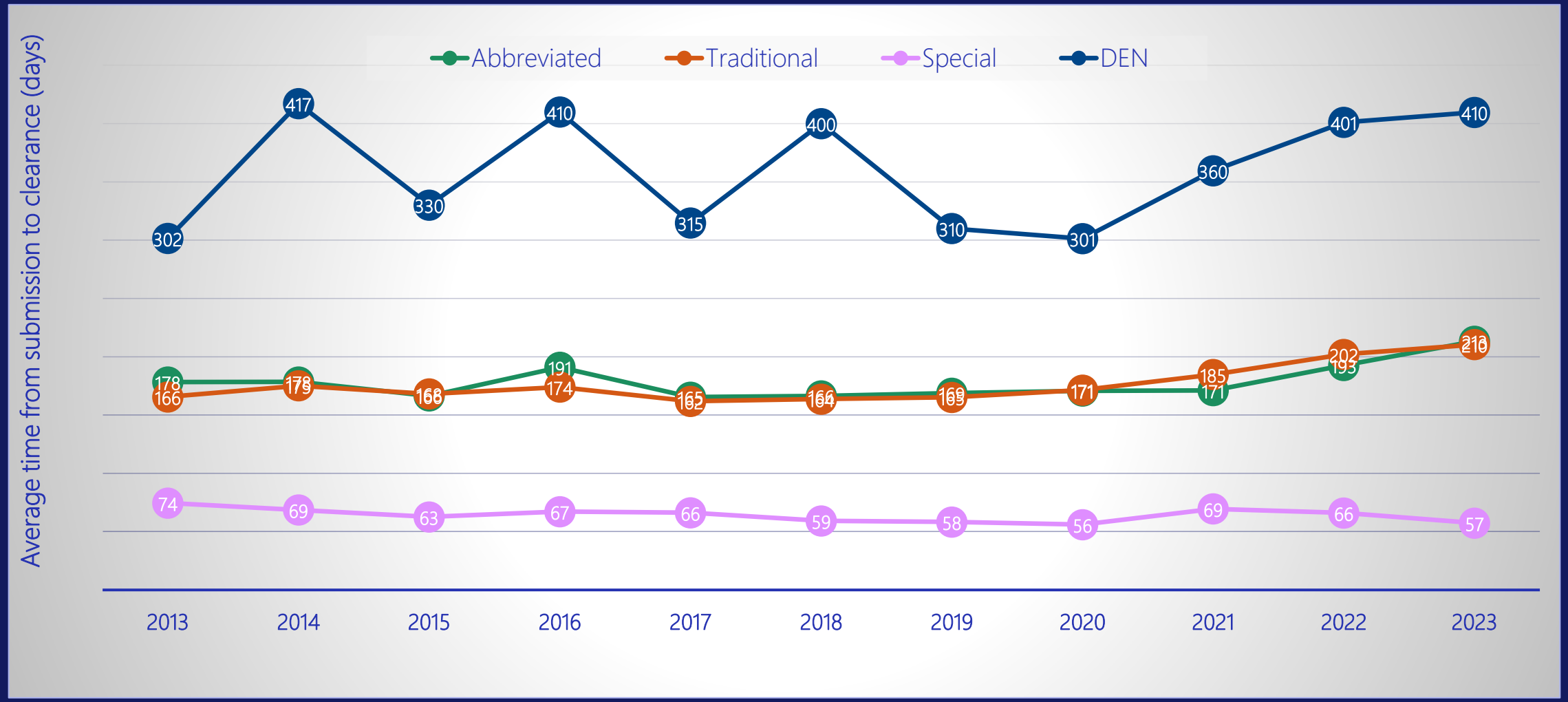


NUMBERS OF 510(K) & DE NOVO CLEARANCES OVER THE YEARS ('96-'22)

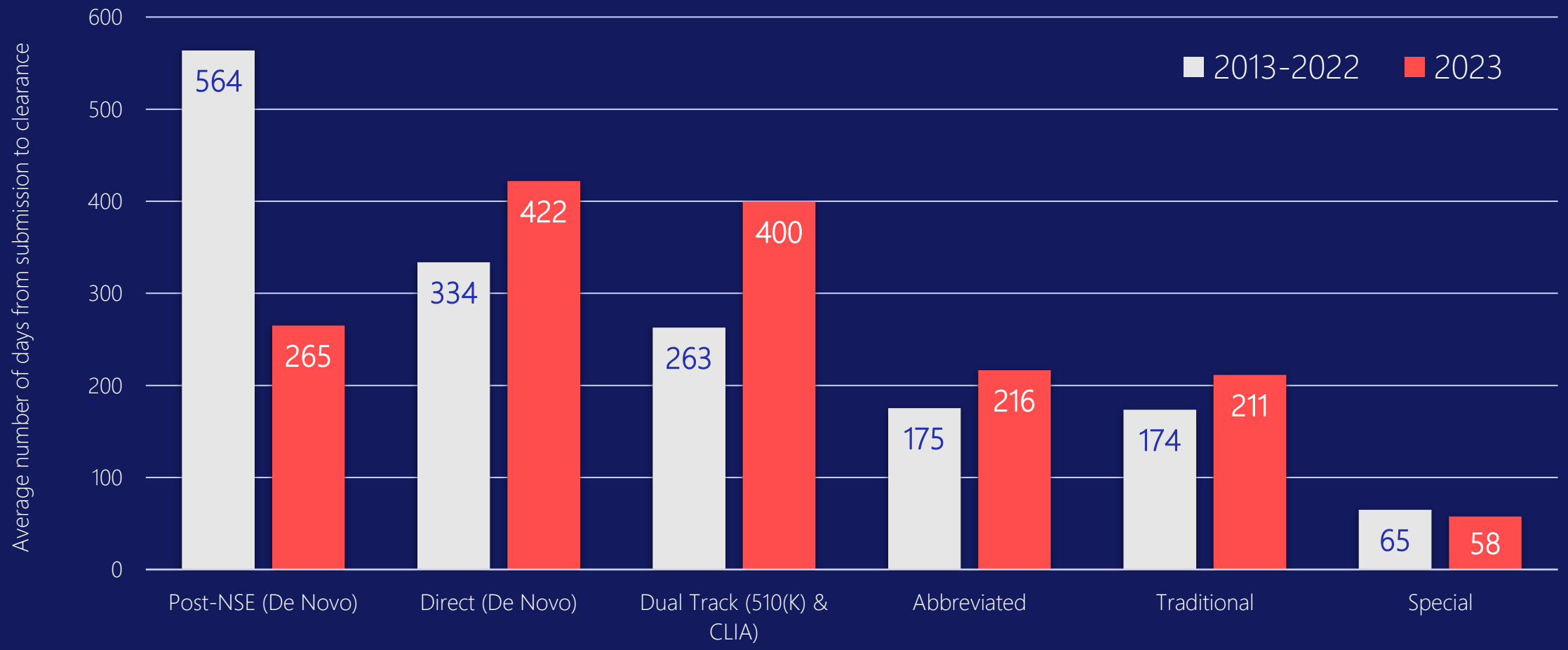
510(K)'S BY SUBMISSION TYPE



CLEARANCE TIME BY SUBMISSION TYPE OVER THE PAST DECADE

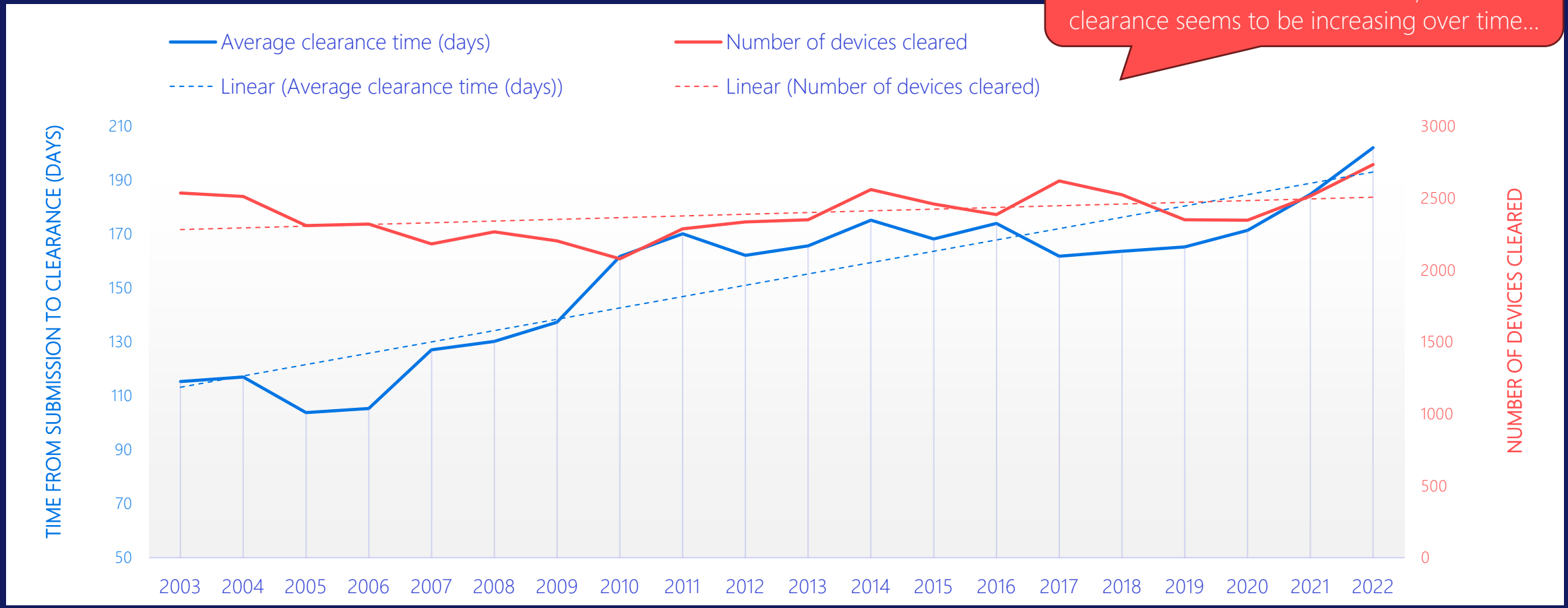


AVERAGE CLEARANCE TIME BY SUBMISSION TYPE 2023 *VS.* PAST DECADE



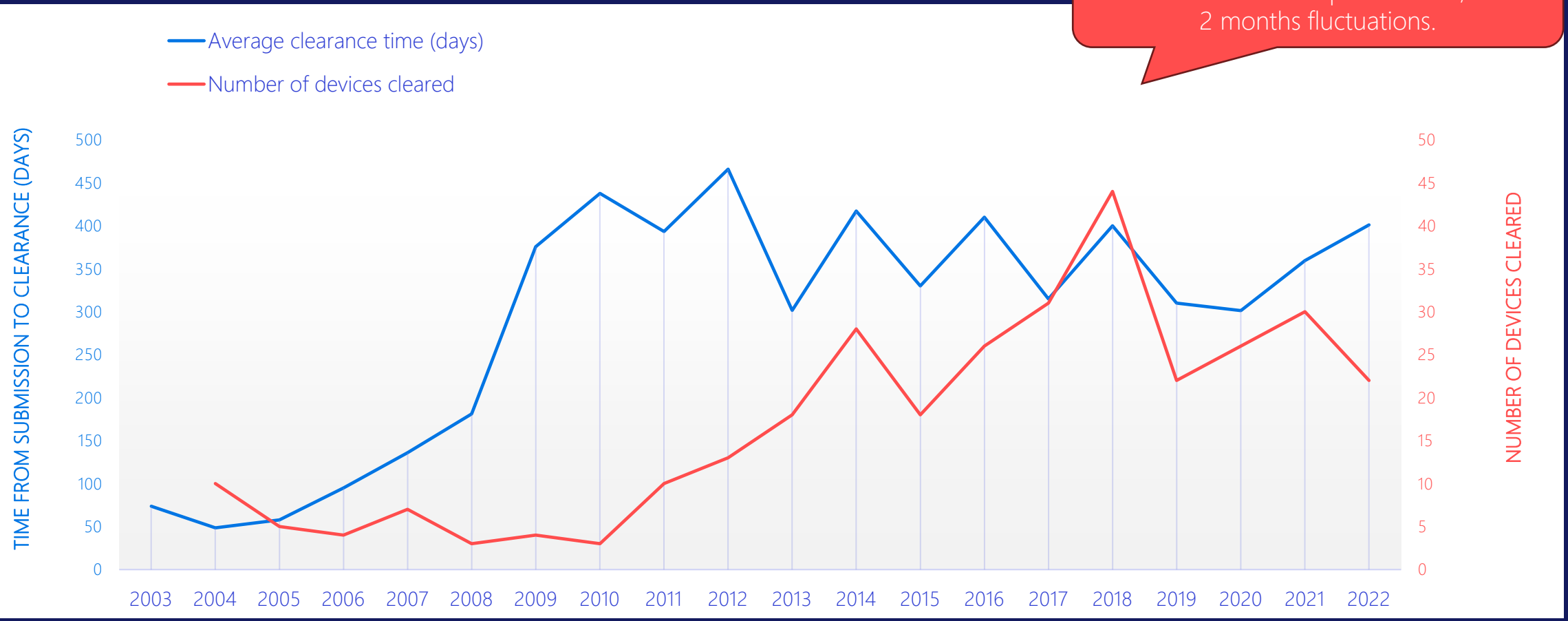
TRADITIONAL 510(K): NUMBERS & CLEARANCE TIME

Although the number of Traditional 510(K) clearances has been rather stable, the time to clearance seems to be increasing over time...



DE NOVO: NUMBERS & CLEARANCE TIME

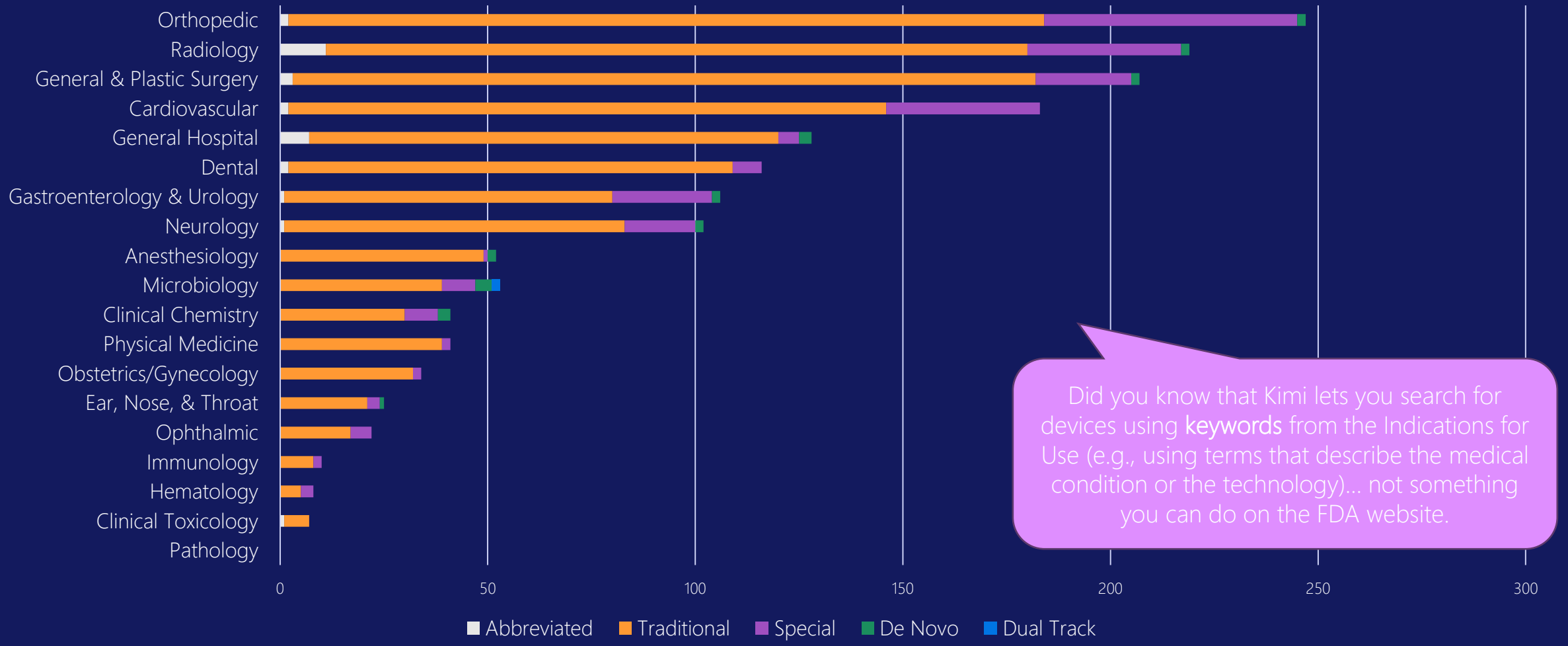
For De Novo's, time to clearance seems rather stable over the past decade, with 1-2 months fluctuations.



LET'S SEE WHAT 2023 LOOKS LIKE, SO FAR

Focusing on clearance times, and comparing to the past decade...

NUMBERS OF 510(K) CLEARANCES IN H1-2023 BY MEDICAL SPECIALTY



Did you know that Kimi lets you search for devices using **keywords** from the Indications for Use (e.g., using terms that describe the medical condition or the technology)... not something you can do on the FDA website.

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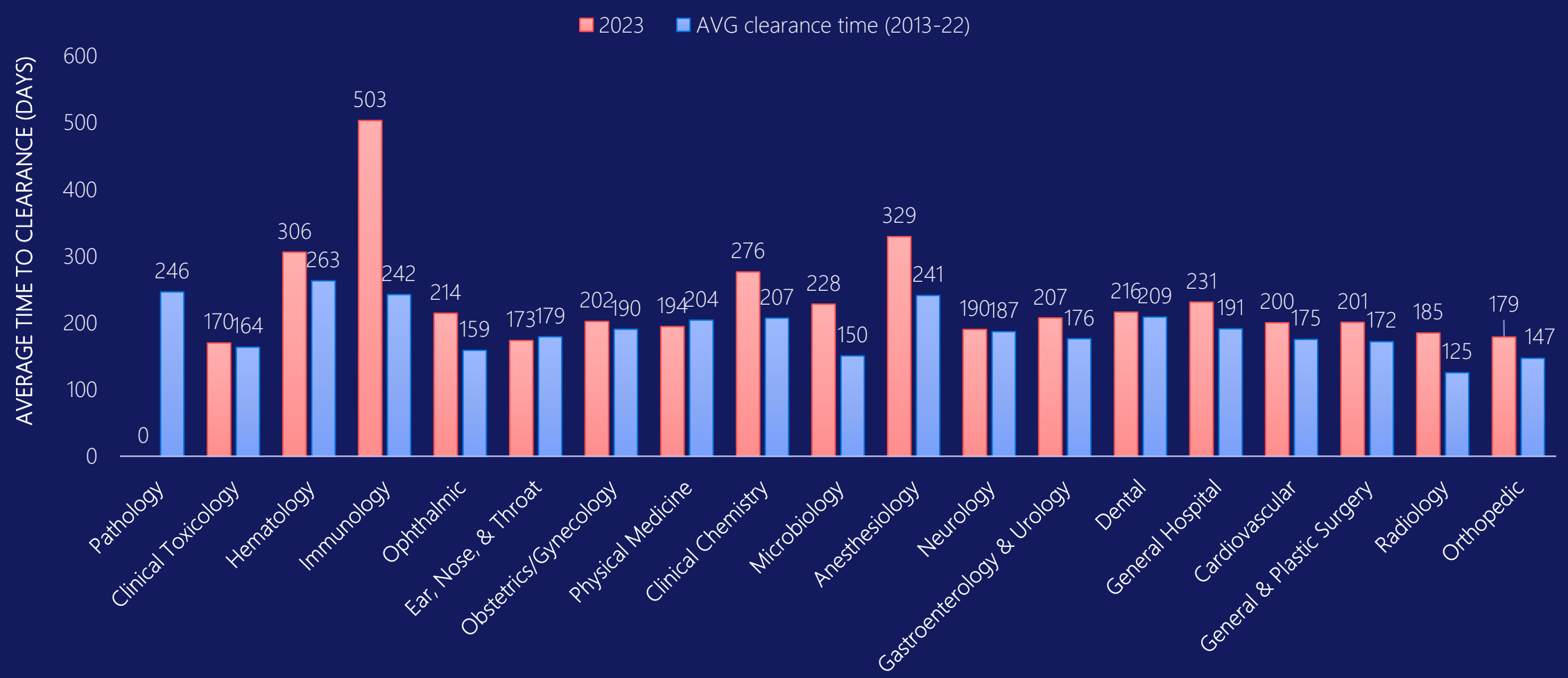
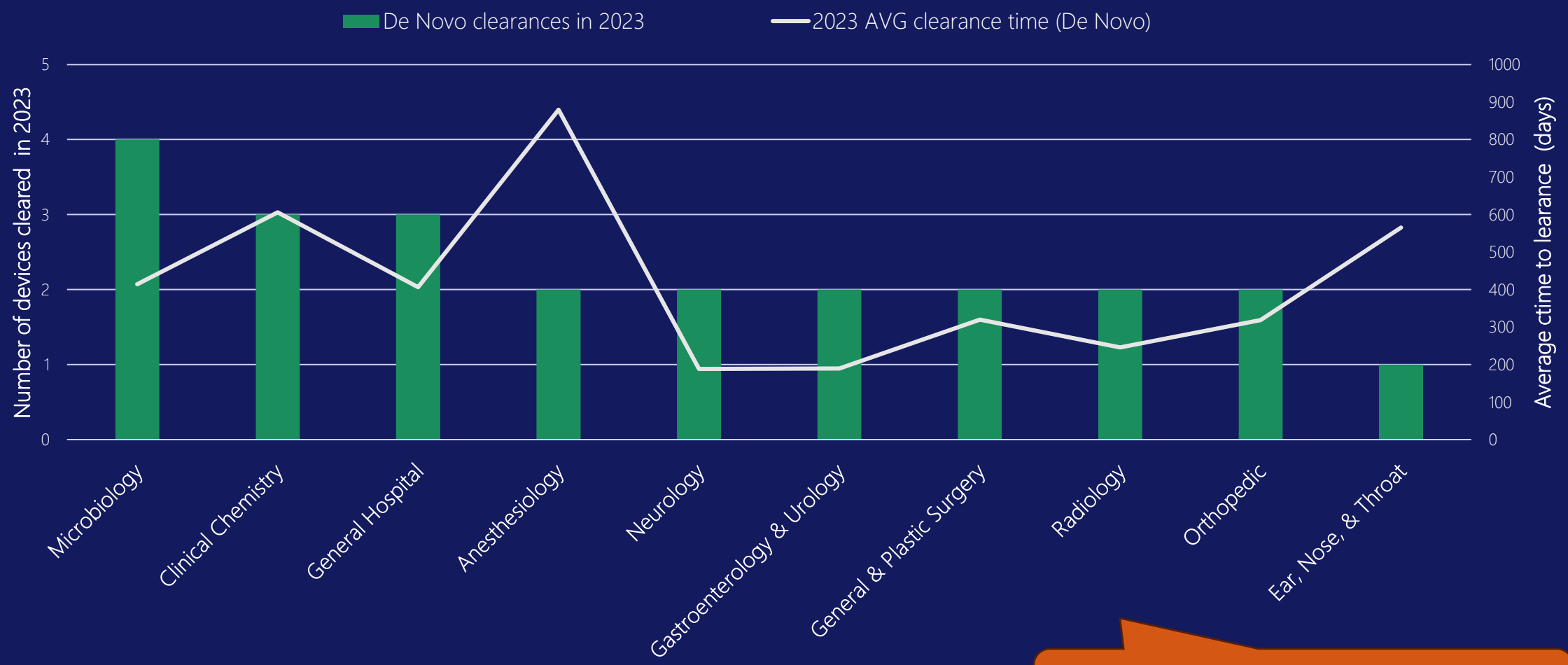
H1-2023 TRADITIONAL 510(K) CLEARANCES & CLEARANCE TIME, BY SPECIALTY

Did you notice the lack of relation between the number of clearances and the time it takes?

TRADITIONAL 510(K) CLEARANCE TIME BY SPECIALTY 2023 *VS.* PAST DECADE



H1-2023 DE NOVO CLEARANCES & CLEARANCE TIME, BY SPECIALTY



Medical specialties not shown are those with no De Novo clearances in 2023, as of yet.

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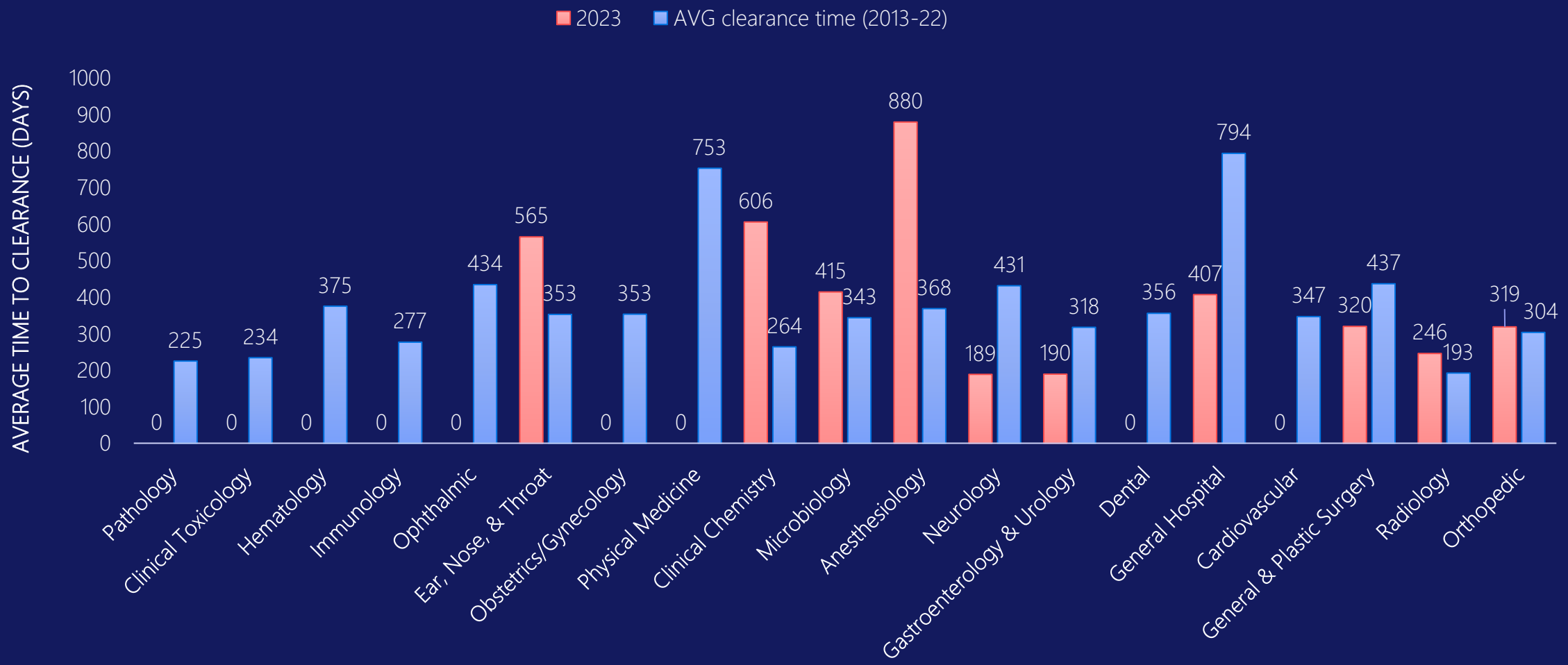
DE NOVO CLEARANCE TIME BY SPECIALTY 2023 VS. PAST DECADE



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SOME FDA TRIVIA BEFORE WE GO...

Number of devices cleared via FDA 510(K) since 1976

166,488

Average number of devices cleared through the 510(K) process each year

3,284

Longest recorded time to get a 510(k) cleared (since 1996)

3,037 days

Device: Silverlon Direct Pressure Wound Closure
Company: Argentum International LLC.
Clearance year: 2007

Specialty with **fastest** average time to clearance (since 1996)

Radiology

Average **98 days** for all 510(K) submission types

Is K000001 the first 510(K) ever cleared?

No!

The first device cleared is **K760001**, by Zimmer Inc.
K000001 is the first device cleared in the new millennium, by Boston Scientific

Specialty with **slowest** average time to clearance (since 1996)

Pathology

Average **215 days** for all 510(K) submission types

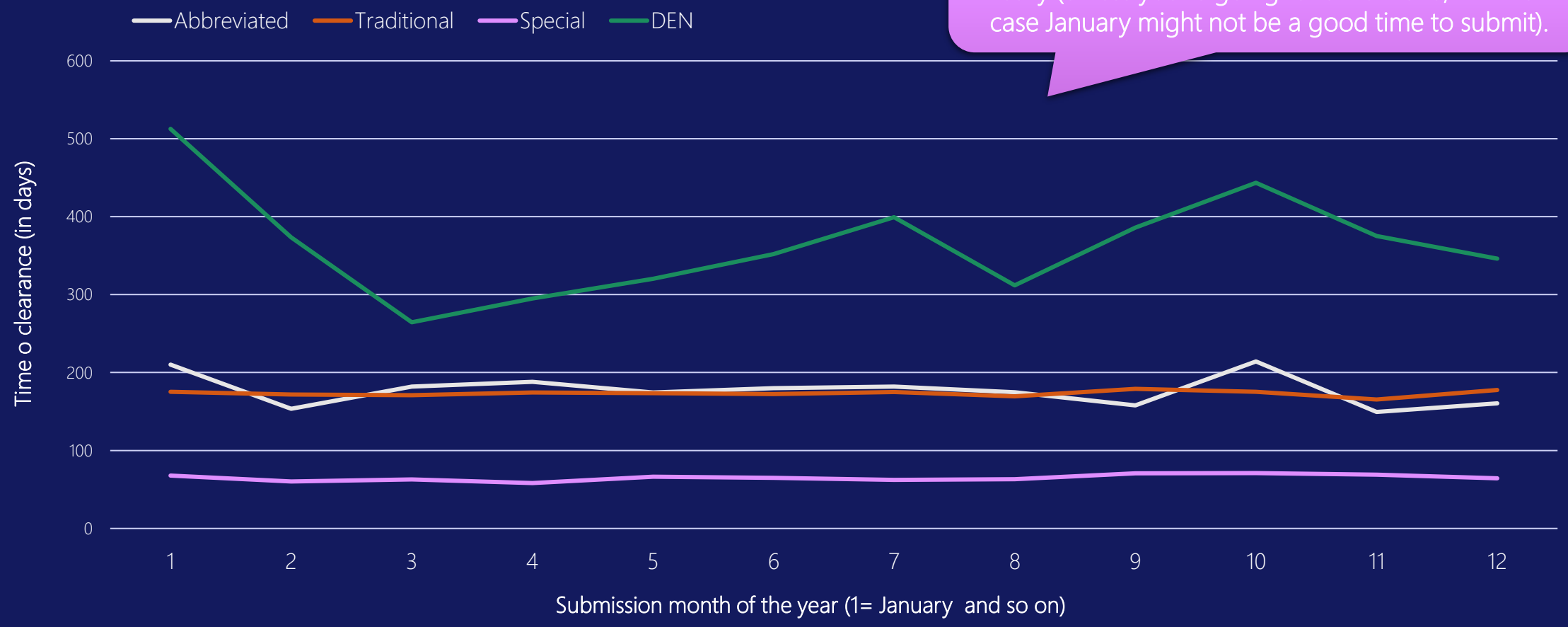
Is it easy and convenient to search for device info on the FDA website?

Heck No!

That's why we created **Kimi**!
If you haven't tried it out yet – feel free to create a free account at: https://app.kimimed.io/registration

PS: 510(K) CLEARANCE TIME BY SUBMISSION MONTH (2013-22)

For those who wondered if there's a better time of year to submit a 510(K)... looks like the answer is: not really (unless you're going for a De Novo, in which case January might not be a good time to submit).



WANT TO SEE MORE ANALYSES LIKE THESE?

Drop us a note at info@kimimed.io and let us know what kind of analytics you'd like to see.

WE HOPE YOU FOUND THIS HELPFUL!

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