New De Novo Guidance/ (Pre-De Novo Submission)

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Background

- **One of 25 Action Items from *FDA's Plan of Action for Implementation of 510(k) and Science Recommendations***
  - **RECOMMENDATION:** "Revise existing guidance to streamline the … *de novo* classification process and clarify its evidentiary expectations…"
  - **PLAN OF ACTION:** "Guidance will outline a streamlined *de novo* pathway as well as recommended content for *de novo* submissions to FDA"
- Original *de novo* guidance released in 1998

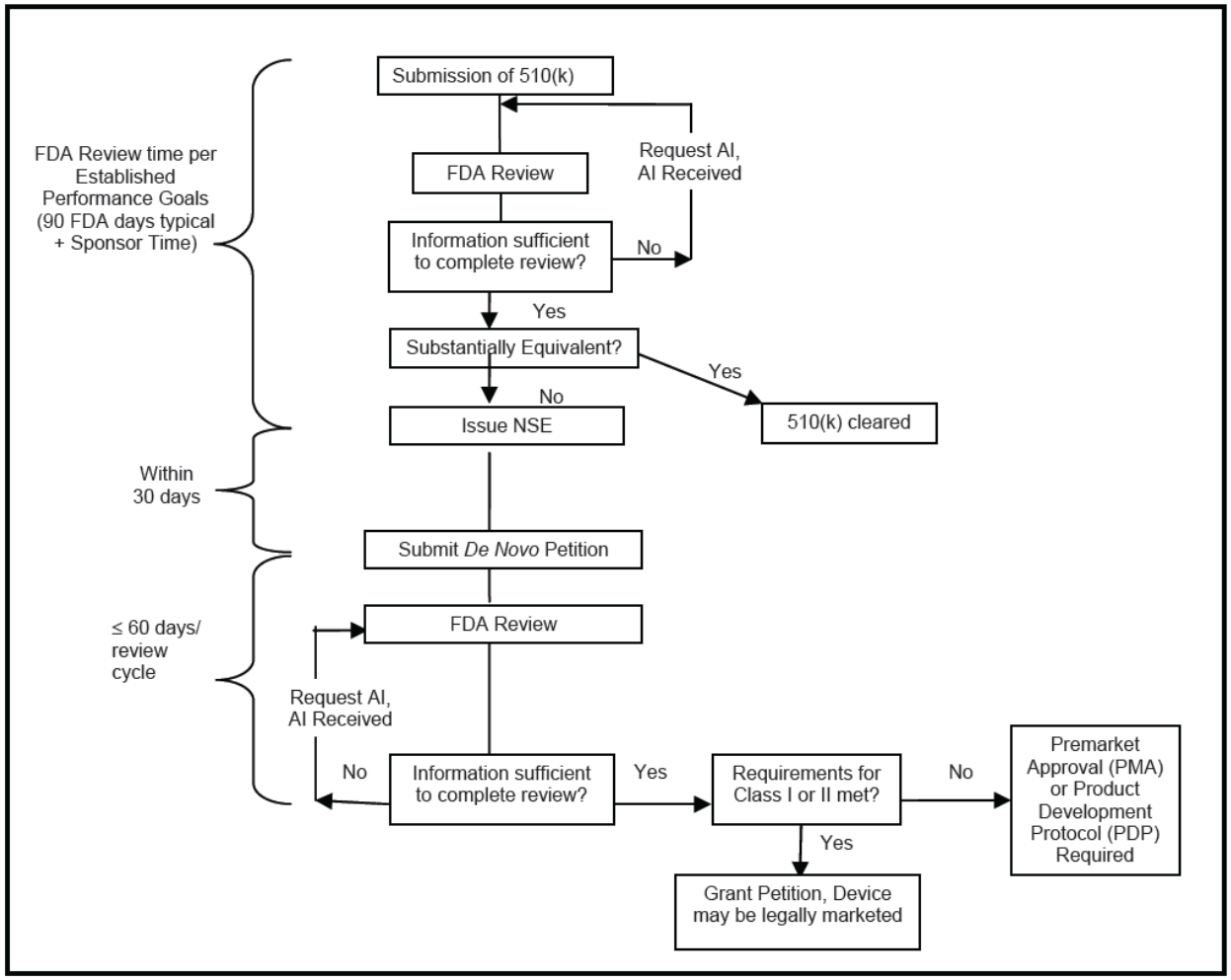
Purpose

- Provide updated recommendations for interacting with FDA regarding devices potentially suitable for *de novo*
- Clarify the FDA review process for *de novo* submissions
- Describe the recommended content of *de novo* submissions

Goals

- Earlier, more productive, discussions between FDA and Industry on potential *de novo* suitable devices
- More comprehensive *de novo* submissions to reduce number of review cycles required
- More transparent and predictable *de novo* review practices

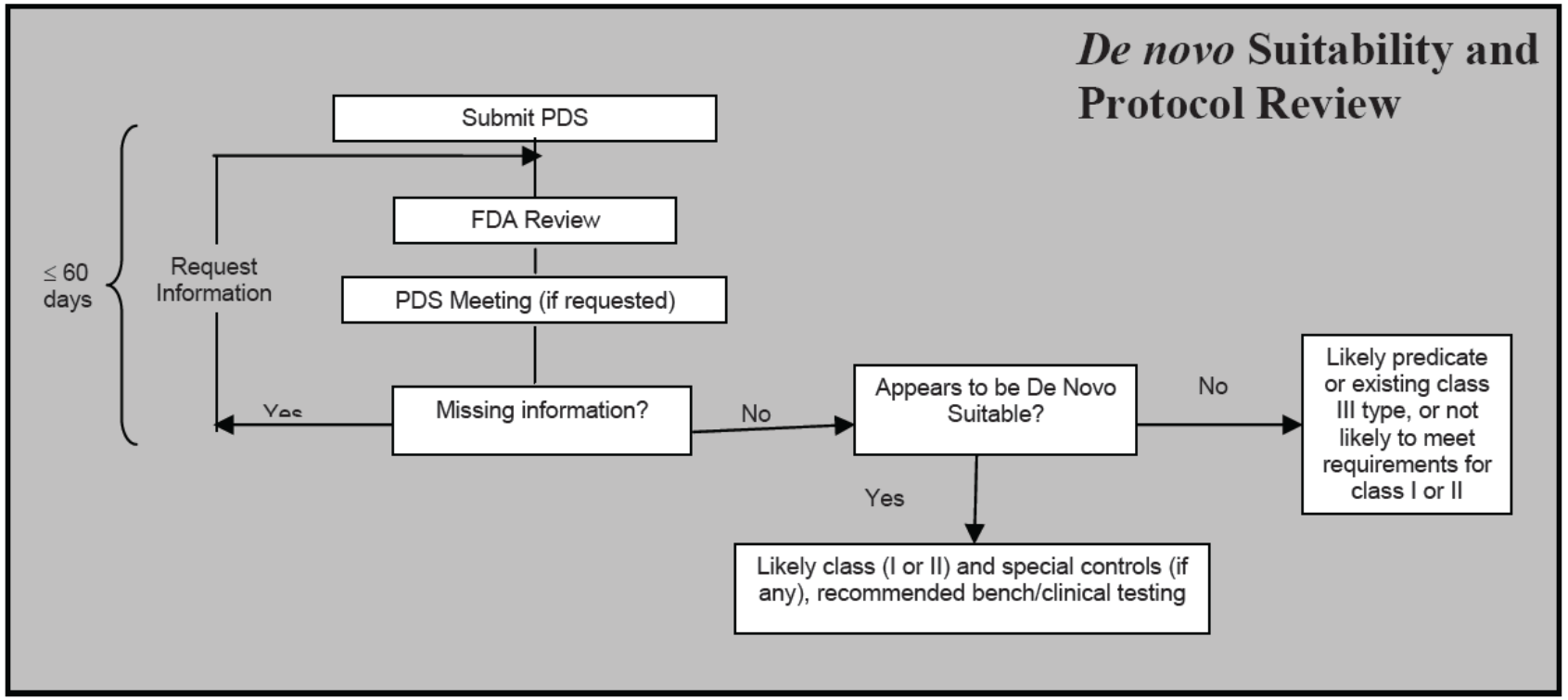
De Novo Review – Traditional



What's New?

- Pre-De Novo Submissions (PDS)
  - Alternate pathway for *de novo* review
    - PDS -> Concurrent 510(k)/*De Novo* petition
    - Traditional 510(k) -> NSE -> *De Novo* petition still acceptable
  - Submit preliminary information in a PDS to determine:
    - Whether FDA believes the device is suitable for *de novo*
    - Likely data requirements and special controls (if applicable)
  - If suitable per a PDS, allows subsequent <u>concurrent</u> submission of 510(k) and *de novo* petition

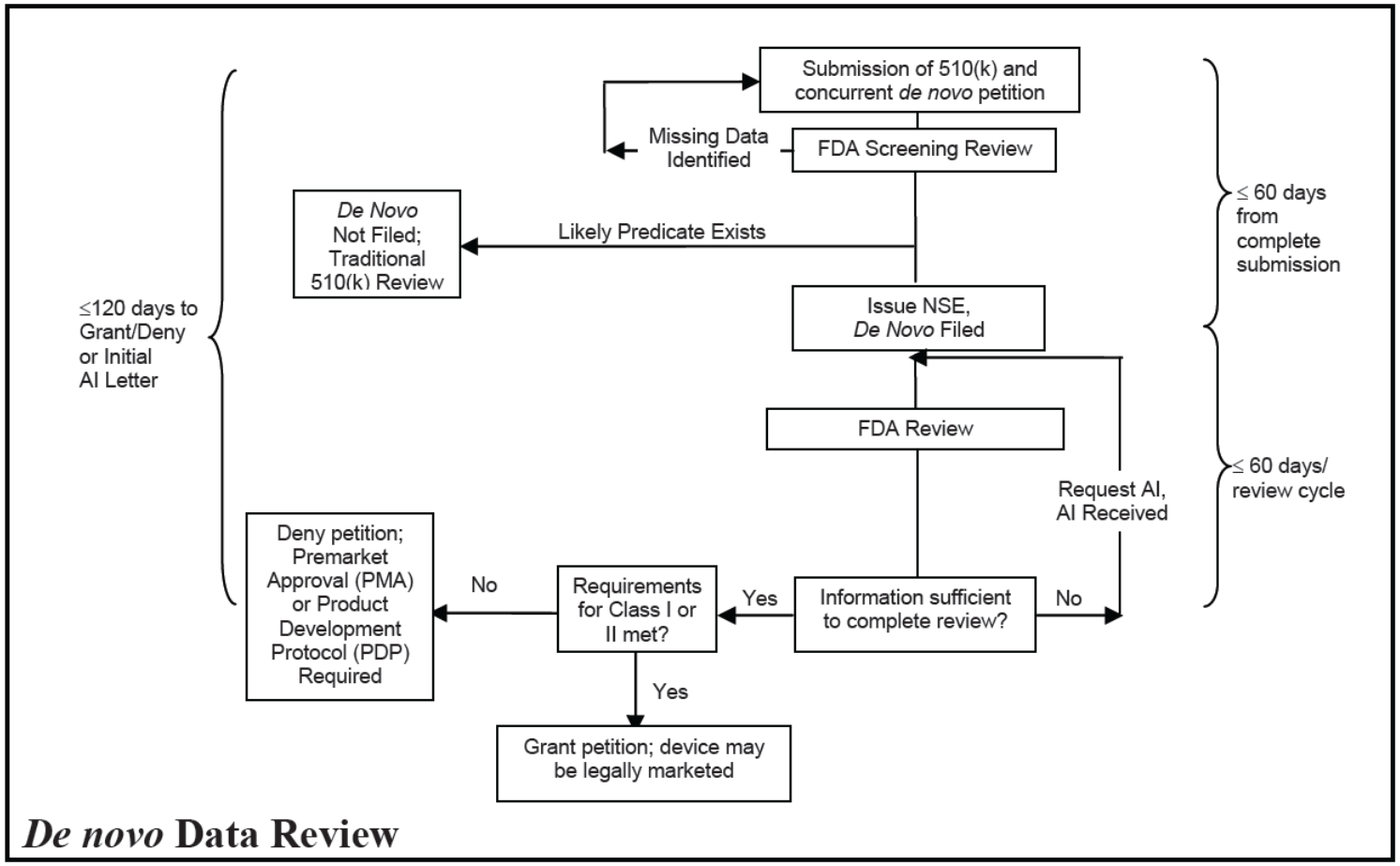
PDS Process


De novo Suitability and Protocol Review
Submit PDS
FDA Review
PDS Meeting (if requested)
Missing information?
Yes
Request Information
≤ 60 days
No
Appears to be De Novo Suitable?
No
Likely predicate or existing class III type, or not likely to meet requirements for class I or II
Yes
Likely class (I or II) and special controls (if any), recommended bench/clinical testing

What's Different?

- Description of FDA review process and timelines for *de novo* submissions
  - Attachments 1 and 2 provide flowcharts of FDA review process
  - PDS's and Petitions are reviewed in 60 day cycles
  - Initial review of concurrent 510(k)/*de novo* petition submissions completed within 120 days

De Novo Review – After PDS



What's Different? (cont.)

- Description of recommended *de novo* submission content
  - Attachment 3 to guidance document
  - PDS and De Novo Petitions have similar content recommendations
    - PDS -> Protocols vs. Petition -> Protocols & Data
    - Recommended Special Controls
    - PDS Only: Classification Summary
    - Post-PDS *De Novo* Petition Only: Change Summary

Comments on the Draft Guidance

- Timelines, Length of overall review
- PDS Letter, Content and obligations
- Implications of “competing” de novos
- Options after a de novo denial
- Criteria for refusing to file or immediately denying
- Recommendations on PDS/de novo petition content
- How de novo decision information is shared

Conclusion

- Guidance is intended to provide additional clarity and more efficient interactions on potential *de novo* suitable devices
- FDA is reviewing the guidance comments in detail and potential legislative changes