Medical Devices: The Interplay between Patent Law and the FDA Regulatory Process

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Transforming Ideas into Opportunities

Overview

- Typical organizational approach to FDA and patent law issues
- FDA Approval Process
- 510(k) clearance
- Intersection of 510(k) clearance and patent law
- De Novo FDA submissions
- De Novo pathway and patent issues
- Conclusions

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Preface

- FDA compliance and patent prosecution/enforcement are typically completely separate endeavors within organizations and universities involved in medical device innovation
- Patentability, validity, and enforceability may be impacted by statements included in FDA submissions:
  - Clinical safety and efficacy
  - Intended use
  - Characterization of technology
  - Competitor devices

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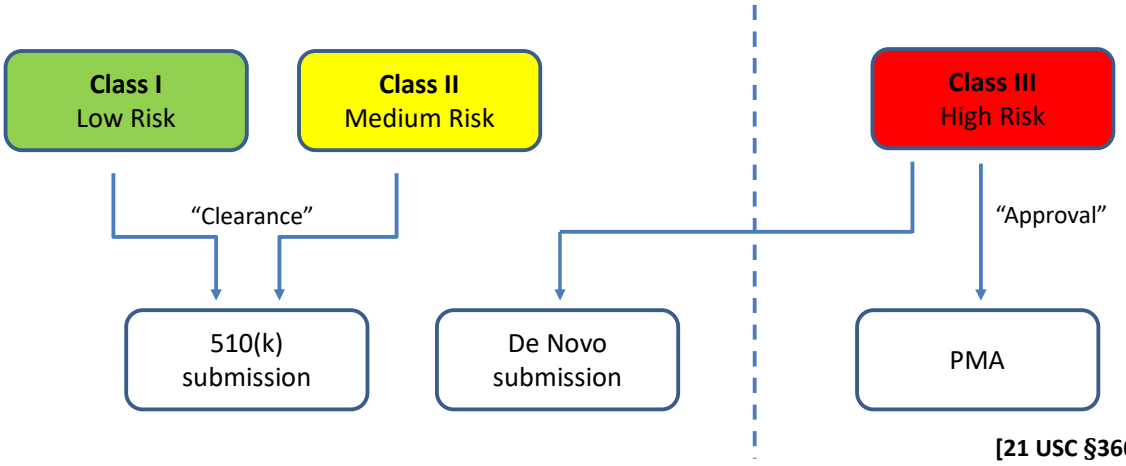
FDA Approval Process



[21 USC §360c]

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FDA Premarket Approval (PMA)

- More rigorous process, costly and time-consuming (years)
- Required for Class III devices:
  - used in **supporting or sustaining human life**;
  - used in **preventing impairment of human health**; or
  - presenting a potentially **unreasonable risk of illness or injury**
- Typically involves submission of:
  - device description and indications
  - marketing and manufacturing information
  - reference to pertinent performance standards
  - preclinical investigatory studies
  - clinical investigatory studies
  - proposed labeling

[21 USC §360e]

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510(k) Clearance
("Premarket Notification")

- 510(k) submissions are **abbreviated** compared to PMA pathway
- Most common route for clearance of medical devices

(Submission ≥ 90 days prior to launch)

[27 CFR §807 Subpart E]

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510(k) Substantial Equivalence

- Identify existing "predicate device" – a legally marketed equivalent device with demonstrated safety and efficacy
  - Can be one of applicant's own devices or a competitor's device
- Assert that new device is "substantially equivalent" to the predicate device
  - If FDA finds substantial equivalence, safety and efficacy are implied

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510(k) Substantial Equivalence

A demonstration of "substantial equivalence" to the predicate device requires:

1) Same intended use AND

2) Same technological characteristics

OR

Different technological characteristics with demonstration that device is at least as safe and effective as predicate device

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510(k) Substantial Equivalence

Statement of Intended Use includes:

- A general description of "diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended."

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510(k) Substantial Equivalence

Technological Characteristics can include:

- Design
- Material
- Chemical composition
- Energy source

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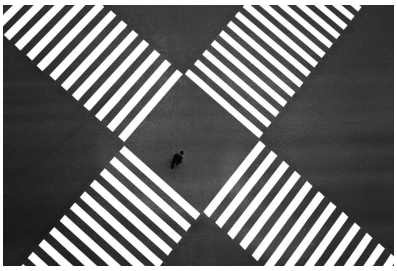
510(k) Clearance and Patent Law

Two key areas of potential intersection:

1) **Patentability and Validity**
   - Novelty
   - Obviousness

2) **Infringement**



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510(k) Clearance and Patentability

Novelty requirement - 35 U.S.C. §102

- A person shall be entitled to a patent unless—
  the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention
- U.S. – one-year grace period
- No grace period in most foreign jurisdictions

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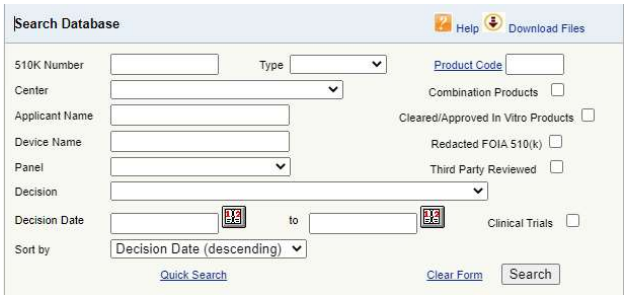
510(k) Clearance and Patentability

- When cleared, decision & 510(k) summary are published on FDA website by the 5th day of the next month



- Supporting information publicly available via FOIA request

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510(k) Clearance and Patentability

Key Takeaway:

File any patent applications before 510(k) submission (or at least publication)

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510(k) Clearance and Patentability

Non-obviousness requirement - 35 U.S.C. §103

- A patent for a claimed invention may not be obtained if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date to a person having ordinary skill in the art
- Involves finding claim elements in various references
- Often, all that is lacking is a motivation to combine the various references

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510(k) Clearance and Patentability

- A patent **applicant's own 510(k) notification** materials may inadvertently provide motivation to combine references or evidence of expectation of success
- Duty of candor to FDA – cannot omit patentable features related to safety and efficacy
- Reliance upon multiple predicate devices may increase risk

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510(k) Clearance and Patentability

Key Takeaways:

- File any patent applications before 510(k) submission (or at least publication)
- Avoid overbroad statements of equivalence extending beyond safety and efficacy (e.g., "identical")
- Only one predicate device is needed – chose carefully and consider assertions of "substantial equivalence"

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510(k) Clearance and Patentability

***Sunrise Medical HHG, Inc. v. AirSep Corp.*, 95 F.Supp. 2d 348, 405-06 (W.D.Pa. 2000)**

- Issue: Statements of substantial equivalence vs. factual summary of technical characteristics

- Sunrise's 510(k) –"*fundamentally repackaged*" versions of predicate devices, but emphasized similarities in dosage methodology ("*identical*" specifications and performance)
- Court disregarded 510(k), stating that its sole purpose was to demonstrate equivalent safety and efficacy
- Substantial equivalence assertion focused on methodology – not the subject matter of the patent claims (device/system claims)

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510(k) Clearance and Patentability

***Sunrise Medical HHG, Inc. v. AirSept Corp.*, 95 F.Supp. 2d 348, 405-06 (W.D.Pa. 2000)**

- Conclusion:
  - A substantial-equivalence assertion can be carefully worded to limit its scope to safety & efficacy
  - However, the accompanying factual assertions can help or hurt, depending on whether they are focused away from or toward the subject matter of the patent claims

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510(k) Clearance and Infringement

- Statements made in 510(k) submissions can resurface long after 510(k) clearance and grant of the patent
- 510(k) may be factually relevant in infringement analysis
  - Direct
  - Indirect (induced or contributory)
  - Doctrine of Equivalents
  - Willfulness

[*See* 35 USC §271]

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510(k) Clearance and Infringement

- "Substantial Equivalence," by itself, does not admit patent infringement
  - Fundamentally different inquiries:
    1) comparison of product to predicate device; and
    2) element by element comparison of patent claim to product
  - Courts have been reluctant to admit 510(k) notifications as evidence in infringement proceedings

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510(k) Clearance and Infringement

- But supporting factual statements made to the FDA can be used in an infringement case
  - "Technological characteristics" may support or refute infringement
    - *U.S. Surgical v. Hospital Prods. Int'l* ., 701 F. Supp. 314, 347 (D. Conn. 1988)(noting that, beyond a generalized "substantial equivalence" assertion, the defendant also stated that "[b]oth devices utilize the same type of disposable cartridges . . . [which] utilize **similar staples, similar anvils, similar staple line configurations, and the same tissue joining methods")**
    - *Univ. of Florida v. Orthovita*, 1:96 CV 82 MMP, 1998 WL 34007129 (N.D. Fla. April 20, 2008)(considering technical chart in 501(k) noting **marked difference between cleared product and predicate device** with regard to patented particle size)

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510(k) Clearance and Infringement

- Doctrine of Equivalents – courts have used factual statements from 510(k) filings to show **functional equivalence**
  - *Mahurkar v. C.R. Bard* , 92 C 4803, 1993 WL 259446 (N.D. Ill. July 6, 1993)(noting that, although the actual 510(k) filing is irrelevant because it is controlled by a different regulatory scheme, the fact that Bard did not retest the Hickman II catheter is probative of functional equivalence)
- Willful infringement – a competitor owning a patent covering the predicate device may use statements from 510(k) as an admission to establish **knowledge of predicate device**

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510(k) Clearance and Infringement

Key Takeaway:

Be aware of the contents of FDA submission (e.g., "technological characteristics") with respect to potential infringement considerations

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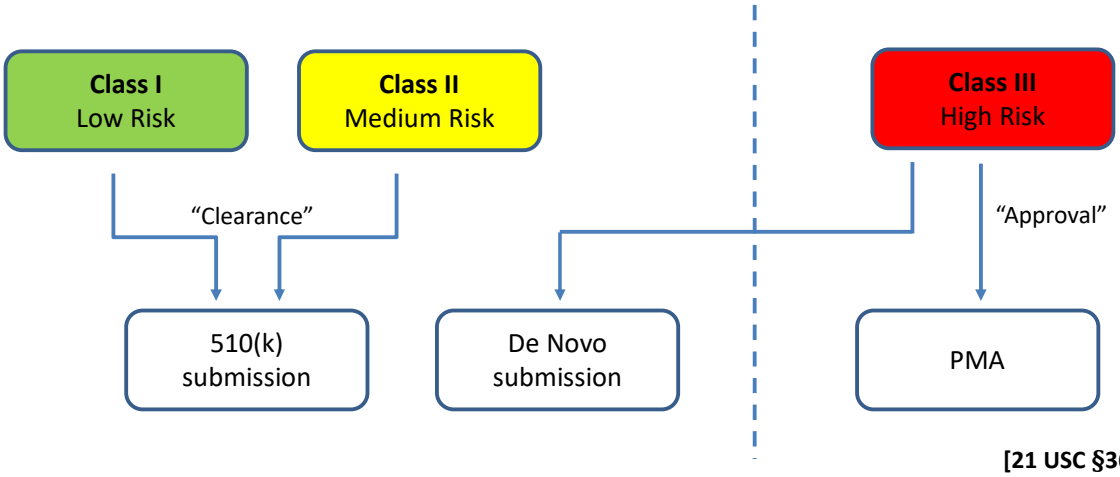
FDA Approval Process



[21 USC §360c]

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De Novo FDA Submissions

- A device that is not "substantially equivalent" to a predicate Class I or Class II device, or for which no predicate device exists, is automatically slotted as new Class III device
- The De Novo process provides a pathway to classify novel medical devices, which would otherwise be Class III due to lack of substantial equivalence, as Class I or Class II
- If approved under De Novo, the device can serve as a predicate for future 510(k) submissions

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De Novo Pathway and Patent Issues

- Newly approved de novo devices serving as predicates for future 510(k) submissions – conflict of interest?
- FDA recently began asking de novo manufacturer to propose their device's "special controls" (e.g., performance standards) used to determine substantial equivalence
  - Must include reasonable assurance of safety and efficacy
  - Likely overlap with core "technological characteristics" (materials, design, energy source, and other device features), which are likely protected by de novo manufacturer's patent!

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De Novo Pathway and Patent Issues

- **Follow-on device 510(k) applicant faces fatal choice**:
  - Admitting same technological characteristics, and therefore patent infringement OR
  - Admitting different technological characteristics, and therefore no substantial equivalence

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De Novo Pathway and Patent Issues

Examples of potential traps for follow-on 510(k) applicants:

- Bose's "self-fitting air-conduction hearing aid" –2018 de novo classification
  - Special controls include **directional sensitivity** as a core feature
  - **Directional sensitivity** claimed in U.S. Pat. No. 10,623,870
- Tandem Diabetes Care "t:slim X2 Insulin Pump" –2019 de novo classification
  - Special controls include **sharing info between pump and digitally connected controls**
  - **Wireless communication means of pump** claimed in U.S. Pat. No. 10,492,141

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De Novo Pathway and Patent Issues

- De Novo pathway could encourage anticompetitive patent strategy
- FDA should carefully review whether de novo applicants' special controls are necessary for safety and efficacy

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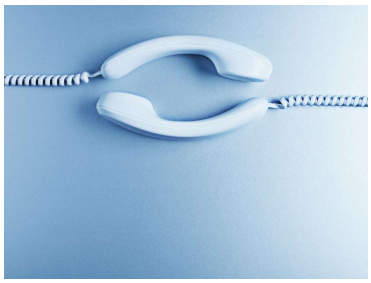
Conclusion

- **Patent counsel and FDA counsel need to talk!**
  - ➢ Ensure coordination between strategies for seeking FDA clearance and patent protection
  - ➢ Avoid potential pitfalls



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Tania is Senior Patent Counsel with 12 years of patent law experience working in the areas of medical devices, biotechnology, and pharmaceuticals. She provides patent and trademark counseling and portfolio management, and provides opinions regarding patentability, freedom-to-operate, infringement, and validity. Tania works with a variety of medical device and biotechnology clients, including Fortune 500 companies, mid-size and start-up companies, and university clients. She has authored a number of publications and given presentations on issues relating to life sciences IP.

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