Pathmaker FDA LAW

Helping Manufacturers and Distributors Get Products to Market

Pathmaker Law takes a comprehensive approach to address client needs with efficiency and thoroughness. The firm clarifies FDA regulatory issues, which enables clients to concentrate on their primary goal of aiding patients while keeping their products compliant.

We help clients bridge the gap between the FDA and industry. The firm has been a trusted advisor on matters including: medical device reporting, 510(k) submissions, Pre-Market Approval (PMA), Investigational Device Exemptions (IDE), clinical trial agreements, data privacy, cybersecurity practices, product labeling, and more.

Our practical experience includes decades of experience working with clients ranging from the largest medical device manufacturer in the world to small startups.

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Services

- Counsel on FDA Regulations:
  - Medical Devices
  - Pharmaceuticals
  - Biologics
  - Food
  - Quality System Regulations
  - Investigational Device Exemptions (IDEs)
  - Investigational New Drugs (INDs)
  - Medical Device Cybersecurity
  - Pharmaceutical cGMP
- Counsel on EU Medical Device Regulations (MDR)
- Counsel on EU In-Vitro Device Regulations (IVDR)
- Counsel on HIPAA regulations and practices
- Product Recalls and Field Actions
- Clinical Trial Agreements
- Quality System Audits
- Advertising and Promotional Review
- Data Privacy
- Product Labeling and Packaging
- Expert Witness Testimony
- Due Diligence for M&A
- Anti-kickback Statute
- Sunshine Reporting

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