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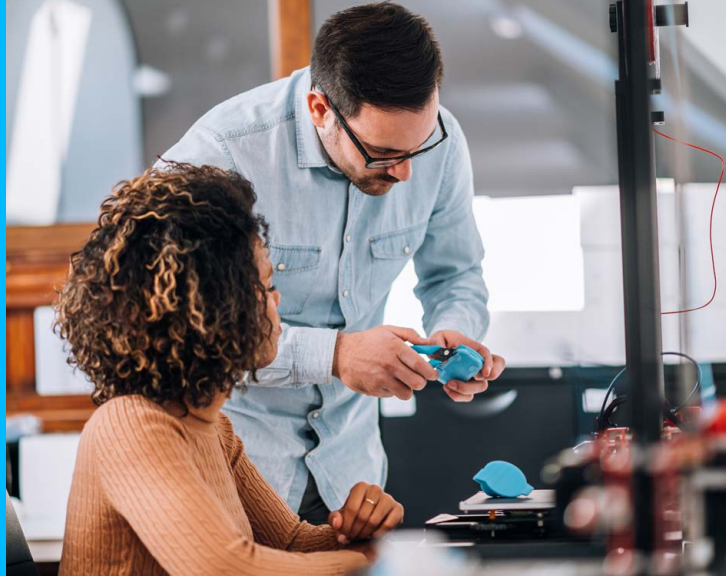
# Medical devices

## Putting FDA regulatory strategy at the heart of medical device development

Shaping a medical device's regulatory strategy in the early stages of development gives companies the maximum flexibility in aligning the device's technology, marketing claims, and regulatory path. It's also an approach that promises to be cost effective as it reduces Food and Drug Administration (FDA) regulatory risks, and makes it more likely that a company will obtain FDA clearance or approval to market a device sooner.

TSG's unique combination of medical device product development capabilities – through our sister company Sagentia Innovation – and in-house FDA regulatory expertise, enables us to put FDA regulatory strategy at the heart of clients' medical device development.

Whether your company is in the initial stages of designing and developing a new medical device or completing the premarket submission, TSG can be your trusted partner in guiding you through the FDA regulatory process.



## We can help:

**Device decisions**
- Statutory definition
- Precedents
- 513(g) Requests for Determination
- Requests for Designation/Pre-RFDs

**Regulatory path determinations**
- Classification regulations
- Product codes
- 513(g)s or Pre-submissions

**Performance data requirements**
- Guidance documents
- Cleared/approved submissions
- Pre-submissions

**Clinical study approval & reporting**
- Investigational Device Exemptions (IDE)
- Institutional Review Boards (IRB)
- Informed consent
- Clinical investigators' financial interests

**Premarket submissions**
- 510(k) Premarket Notifications
- *De Novo* Requests
- Humanitarian Device Exemptions (HDE)
- Premarket Approvals (PMA) & Supplements
- Responses to FDA's information requests

**Representative at FDA meetings**
- Preparation/mock meetings
- FDA feedback assessment
- Clarification
- Advocacy for device/data
- Negotiations
- Meeting minutes acceptance
- Strategy refinement

**Other premarket issues**
- Pending 510(k)s
- Exemption documentation
- Establishment registration
- Device listing

**Postmarket compliance**
- Medical Device Reports
- Corrections and removals (recalls)
- Labeling
- Device modifications
- IDE and PMA Reports
- Practice of Medicine Exception

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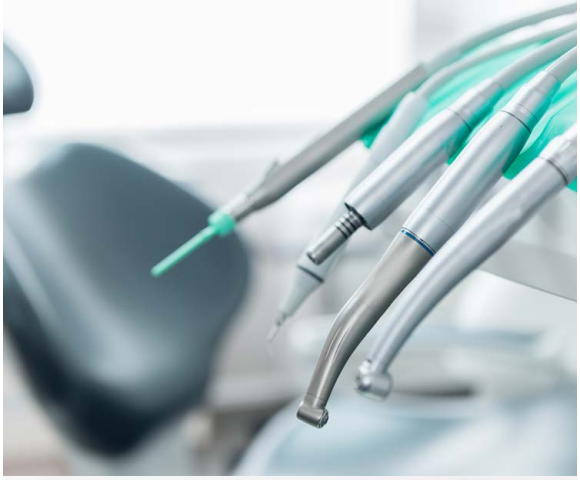
## Medical specialties

Experienced in providing regulatory advice to companies ranging from small start-ups to multinational corporations, our expertise covers a broad spectrum of medical devices within the following specialties:

- Anesthesiology
- Cardiovascular
- Dental
- Ear, Nose, and Throat (ENT)
- Gastroenterology and urology
- General and plastic surgery
- General hospital and personal use
- *In vitro* diagnostics
- Obstetrics and gynecology
- Ophthalmology
- Orthopedic
- Neurology
- Physical medicine
- Radiology



## Experienced team

TSG's medical device regulatory practice is led by Laurie Clarke, JD, MPP, AB. Her 25+ years' experience practicing FDA law, including being a FDA partner at three top-ranked law firms, enables her to effectively advise and advocate for clients throughout a device's life cycle. Laurie specializes in helping medical device companies develop and implement regulatory strategies that meet their marketing objectives. She has a law degree from Stanford University and a Masters in Public Policy, with a concentration in health policy, from Harvard University, as well as an undergraduate degree from Smith College.

## Why TSG Consulting?

**Proven –** 30+ year history and 25+ years of FDA regulatory experience

**Comprehensive strategy –** FDA and EPA experts create a unified regulatory strategy for products regulated by both agencies

**Integrated device design and regulation –** Collaboration with medical device advisory and product development colleagues at sister company Sagentia Innovation produces a complementary device design and regulatory strategy that evolve together

**One-team approach –** Hands on, collaborative

**Flexible –** Partner for entire life cycle of a device or for a specific project

**Global presence –** 10 offices across the US (DC & California), Canada, UK and EU (France, Germany and Spain)

## TSG Consulting

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Interested in discussing a potential project?

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