Medical Device Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

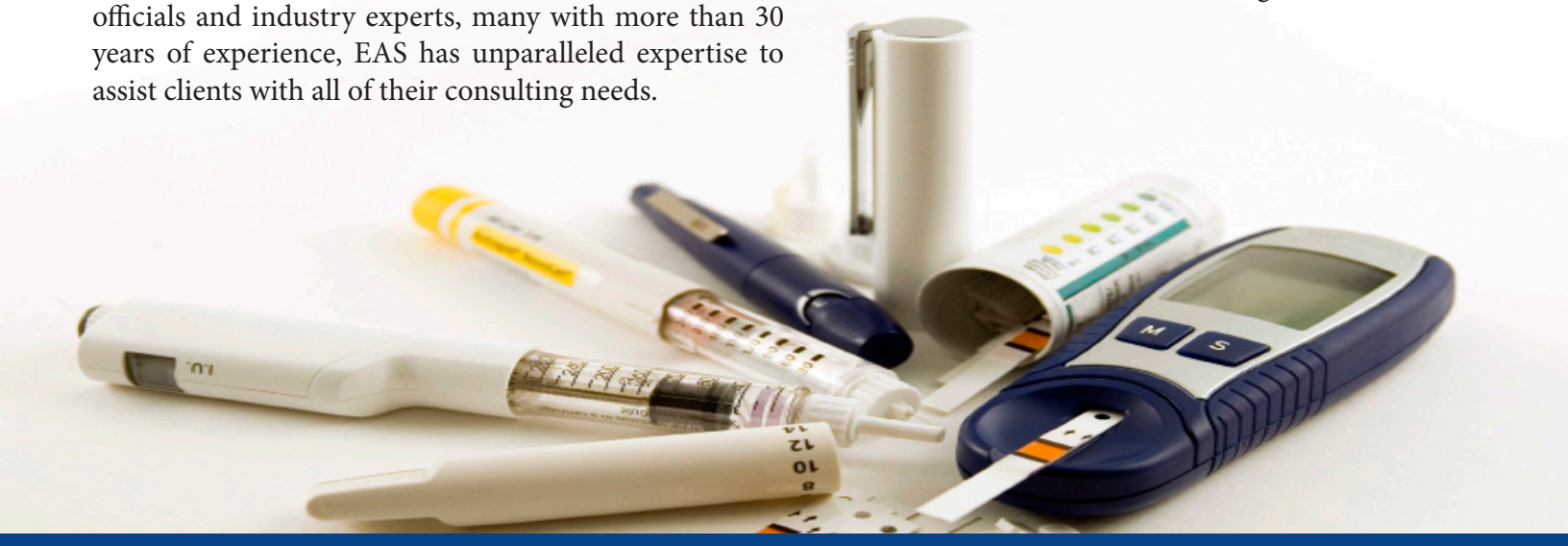
Whether your medical device product is a class I, II or III, EAS Consulting Group has the expertise to provide wide-reaching guidance and act as a conduit between manufacturers and marketers of medical devices and the FDA.

We offer assistance for submissions such as 510(k), Pre-Subs and De Novo Premarket Clearance, as well as IDE. We conduct QSR audits and facilitate ISO 13485 GMP harmonization.

Our firm also acts as a US Agent, providing registration assistance, filing petitions, exemptions and responding to warning letters and 483s.

We have been a leading provider of regulatory services to FDA regulated industries for over 50 years, helping clients develop regulatory strategies, implement quality systems, and ensure compliance with all FDA regulations. Employing a unique team of former FDA officials and industry experts, many with more than 30 years of experience, EAS has unparalleled expertise to assist clients with all of their consulting needs.

- ✓ Regulatory Strategy Development
- ✓ Regulatory Compliance
- ✓ 510(k) Pre-Market Clearance, De Novo and Pre-Subs, 513 (g) and submissions
- ✓ ISO 13485 QSR and FDA GMP harmonization
- ✓ CAPA, FDA 483 & WL Remediation
- ✓ Facility and SOP Audits
- ✓ Label Assistance
- ✓ Design History and Device Master Files
- ✓ Assistance with Detained Products
- ✓ US Agent Services
- ✓ Seminars and Onsite Trainings



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