

FDA 510(k) Submissions

Qserve offers a wide range of services to medical device companies that are seeking regulatory approval for their products in the US. Qserve's Consultants have a wealth of experience in the preparation of regulatory submissions required to obtain FDA marketing clearance and approval and have built strong relationships with the FDA. We can advise on the best strategies for filing and compliance, and help you avoid the common pitfalls and delays. Qserve can minimize the time and costs involved, and maximizing your product revenues.

510(k) or Pre-Market Notification

This is the primary mechanism by which medical devices are accepted to the market in the US and generally applies to Class II devices. Its purpose is to demonstrate to the FDA that the device to be marketed is "substantially equivalent" to another that has already been accepted through the 510(k) process. Most devices, unless they employ novel technologies or applications, can be submitted for review under this process. The FDA will require data to back substantial equivalence claims, descriptive data and performance data, to support this type of submission.

IDE or Investigational Device Exemption

New devices cannot be trialed in human subjects without prior permission from the FDA and an Institutional Review Board (IRB). The application filed for this approval is called an Investigational Device Exemption (IDE). It allows for the investigational medical device to be used in a clinical study to collect safety and effectiveness data, in support of a Pre-Market Approval (PMA, see below) application or a 510(k) submission to the FDA.

PMA or Pre-Market Approval

This involves the formal approval of the FDA regarding the safety and effectiveness of the medical device based on valid device related scientific data and rationale, rather than just a comparison to a predicate device, as in the 510(k) process. PMA submissions require the inclusion of clinical data. This process applies to Class III medical devices, which involve the most novel and complex technologies and such applications are subject to rigorous scrutiny by the FDA.

Whether it is a 510(k), IDE or PMA that applies to your medical device, Qserve global consultants will successfully guide you through the entire process. We advise on and/or carry out the following activities on your behalf:

- GAP Analysis (a first assessment to verify what is needed)
- Regulatory document preparation and submission (Regulatory Opinion Letter, 510(k), IDE, PMA, Device Master File (DMF))
- Quality management system development, implementation, management, auditing and training (FDA/QSR, GMP, GLP, GCP, ISO 9000, ISO 13485 compliance)
- Validation services in relation to products, design control, and other processes such as purchasing, logistic and production
- New Technology Assessment, Business Development and Medicare Reimbursement
- US Agent and Official Correspondent
- Assistance with or writing contracts for suppliers/subcontractors
- Experienced Consultants who work closely with you to ensure timely and on budget filing of the submissions

If you would like more information or a free consultation and price quotation, please contact us.