

TPRG is accredited by the FDA to review Medical Device Submissions on their behalf as part of the Third Party Review Program. By fast tracking clients' submissions, we reduce time to market by 90-120 days saving time and increasing revenues. The program is designed to support and complement the standard FDA review cycle by providing the Medical Device Industry the option for a faster review process.



We provide insight into current FDA compliance concerns

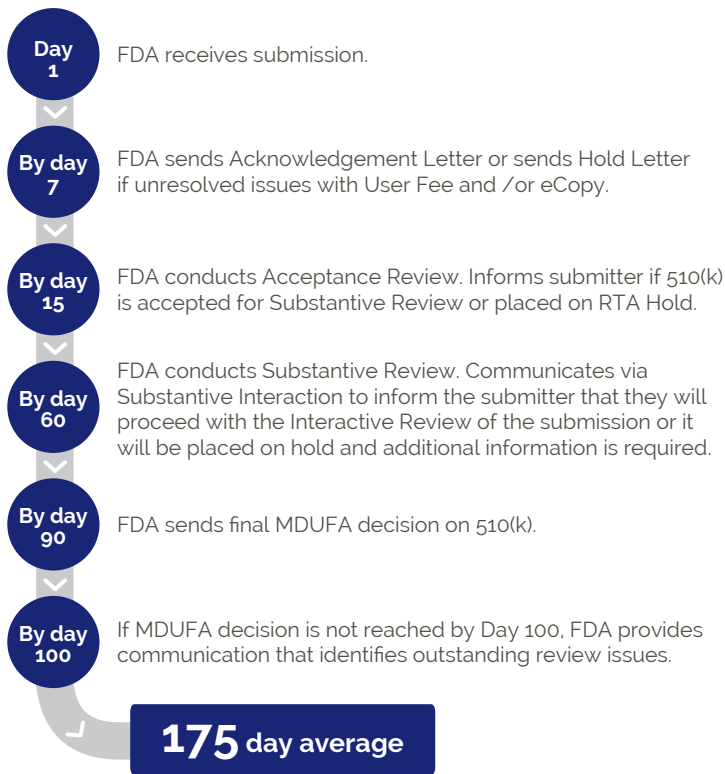


We maintain open lines of communication

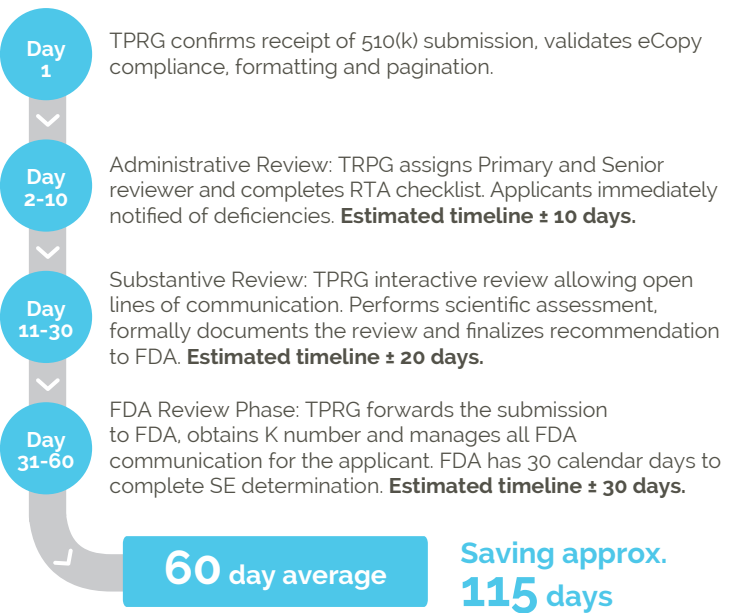


We are FDA MDUFA fee exempt

**Traditional 510(k) Review Cycle Timeline:
2018 FDA Standard Review Cycle**

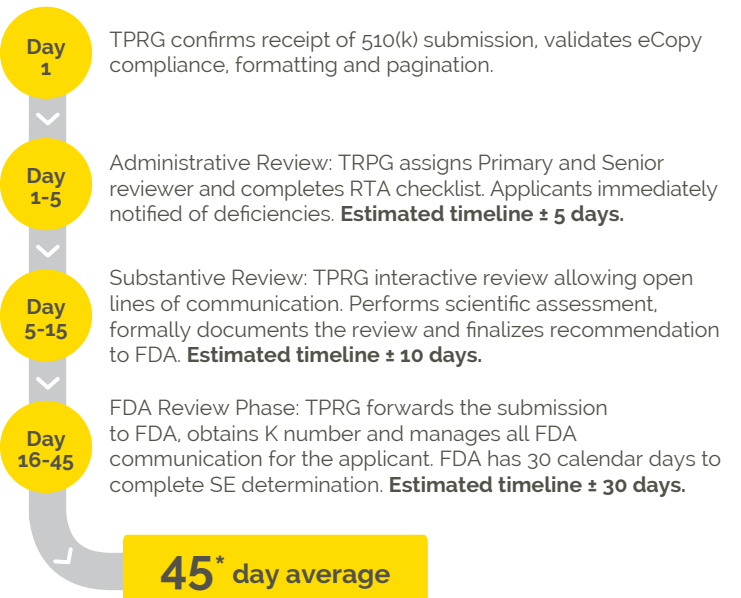


**Traditional 510(k) Review Cycle Timeline:
2018 TPRG Standard Review Cycle**

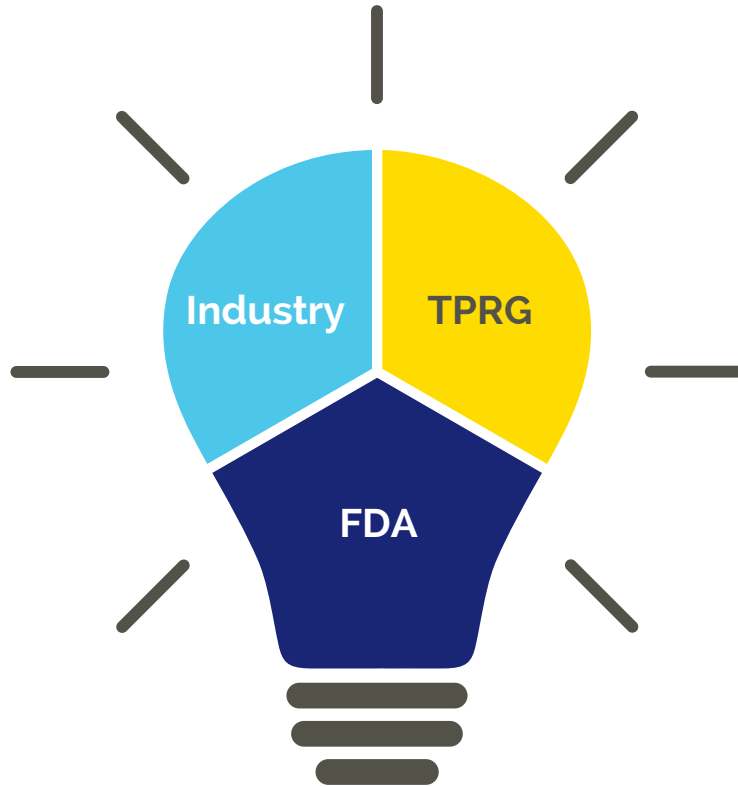


TPRG review capabilities include the review and substantial equivalence determination for 510(k) submissions.

Special 510(k) Cycle Timeline



*Requires applicant to provide access to the predicate device submission



FDA Branch Accreditations

- Anesthesiology
- Cardiovascular
 - Dental
- Ear Nose and Throat
- Gastroenterology
- General and Plastic Surgery
 - General Hospital
 - Immunology
- Obstetrics/Gynecology
 - Ophthalmic
 - Orthopedic
- Physical Medicine
 - Radiology

Client Advantages

- ✓ SE clearance up to 90 - 120 days faster
- ✓ Increased revenue opportunities
- ✓ Exempt from paying FDA MDUFA
- ✓ Direct communication with review team

TPRG Capabilities Cover

- 7 7 FDA office of device evaluation divisions
- 14 14 device branches
- 1.2k Over 1,200 product codes
- 23 23 accredited reviewers available

FDA Accredited 510(k) Third Party Reviewer