FDA Accredited Expedited 510(k) Review and Clearance

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

- **Day 1** — FDA receives submission.
- **By day 7** — FDA sends Acknowledgement Letter or sends Hold Letter if unresolved issues with User Fee and /or eCopy.
- **By day 15** — FDA conducts Acceptance Review. Informs submitter if 510(k) is accepted for Substantive Review or placed on RTA Hold.
- **By day 60** — FDA conducts Substantive Review. Communicates via Substantive Interaction to inform the submitter that they will proceed with the Interactive Review of the submission or it will be placed on hold and additional information is required.
- **By day 90** — FDA sends final MDUFA decision on 510(k).
- **By day 100** — If MDUFA decision is not reached by Day 100, FDA provides communication that identifies outstanding review issues.

175 day average

Traditional 510(k) Review Cycle Timeline:

2018 TPRG Standard Review Cycle

- **Day 1** — TPRG confirms receipt of 510(k) submission, validates eCopy compliance, formatting and pagination.
- **Day 2-10** — Administrative Review: TRPG assigns Primary and Senior reviewer and completes RTA checklist. Applicants immediately notified of deficiencies. **Estimated timeline ± 10 days.**
- **Day 11-30** — Substantive Review: TPRG interactive review allowing open lines of communication. Performs scientific assessment, formally documents the review and finalizes recommendation to FDA. **Estimated timeline ± 20 days.**
- **Day 31-60** — FDA Review Phase: TPRG forwards the submission to FDA, obtains K number and manages all FDA communication for the applicant. FDA has 30 calendar days to complete SE determination. **Estimated timeline ± 30 days.**

60 day average

Saving approx. **115** days

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

Special 510(k) Cycle Timeline

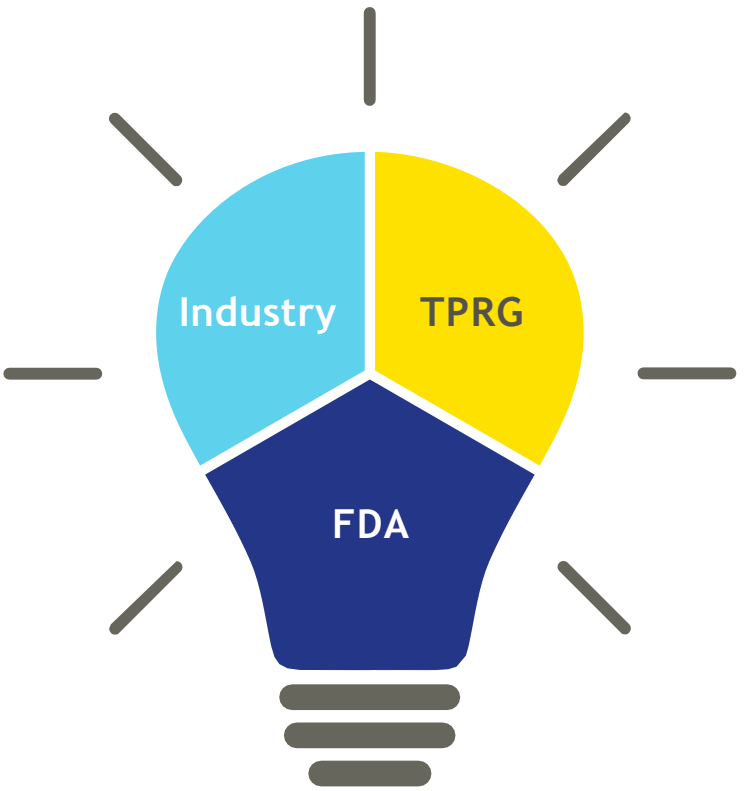
- **Day 1** — TPRG confirms receipt of 510(k) submission, validates eCopy compliance, formatting and pagination.
- **Day 1-5** — Administrative Review: TRPG assigns Primary and Senior reviewer and completes RTA checklist. Applicants immediately notified of deficiencies. **Estimated timeline ± 5 days.**
- **Day 5-15** — Substantive Review: TPRG interactive review allowing open lines of communication. Performs scientific assessment, formally documents the review and finalizes recommendation to FDA. **Estimated timeline ± 10 days.**
- **Day 16-45** — FDA Review Phase: TPRG forwards the submission to FDA, obtains K number and manages all FDA communication for the applicant. FDA has 30 calendar days to complete SE determination. **Estimated timeline ± 30 days.**

45* day average

*Requires applicant to provide access to the predicate device submission

TPRG
THIRD PARTY REVIEW GROUP

Capabilities and Client Advantages



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

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www.fdathirdpartyreview.com