Who We Are and What We Do

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 this reduces 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.

Insight Into Current FDA Compliance Concerns

Open Communication Channels

FDA MDUFA Fee Exempt

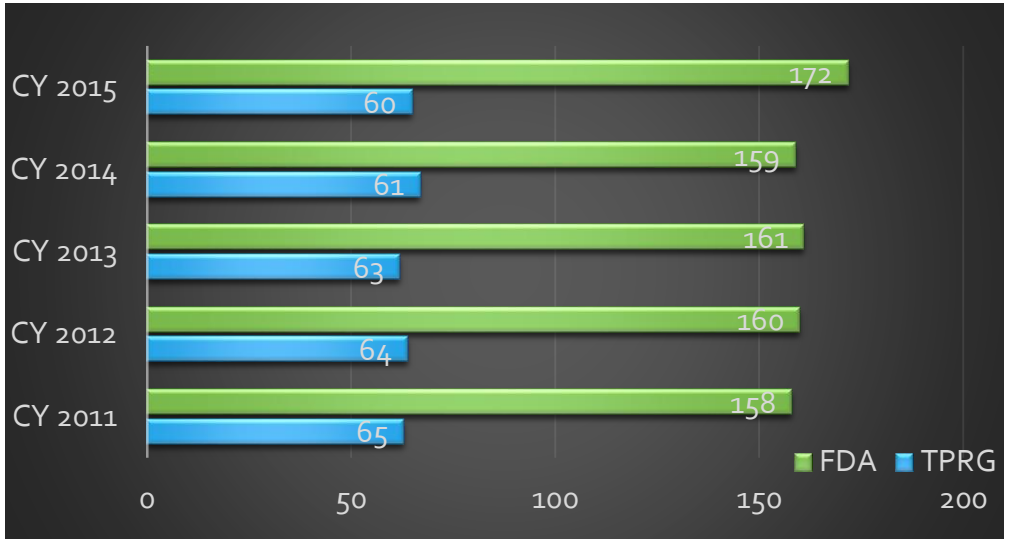
Optimizes Staff Availability for Other Projects

Enhanced Revenue Opportunity

Administrative Workload Lifted

How We Can Save You 100 Days!

Time to market matters! Consider the potential revenue that could be generated by obtaining clearance 3-4 months earlier by using TPRG. As an example, a cleared medical device sold at a unit cost of $8,500, factoring a projected sales of 10 devices per month over a 100 day period, would yield additional company revenue valued at $255,000.



We understand the need for industry to obtain FDA clearance as soon as possible. Since the inception of TPRG, submissions reviewed by FDA averaged approximately 162 days over the past 5 years. During this same time, submissions reviewed by TPRG averaged 60 days.

Traditional 510(k) Review Cycle Timeline

2015 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.

172 Day Average

2015 TPRG Standard Review Cycle

Day 1
- TPRG confirms receipt of 510(k)submission, validates eCopy compliance, formatting and pagination.

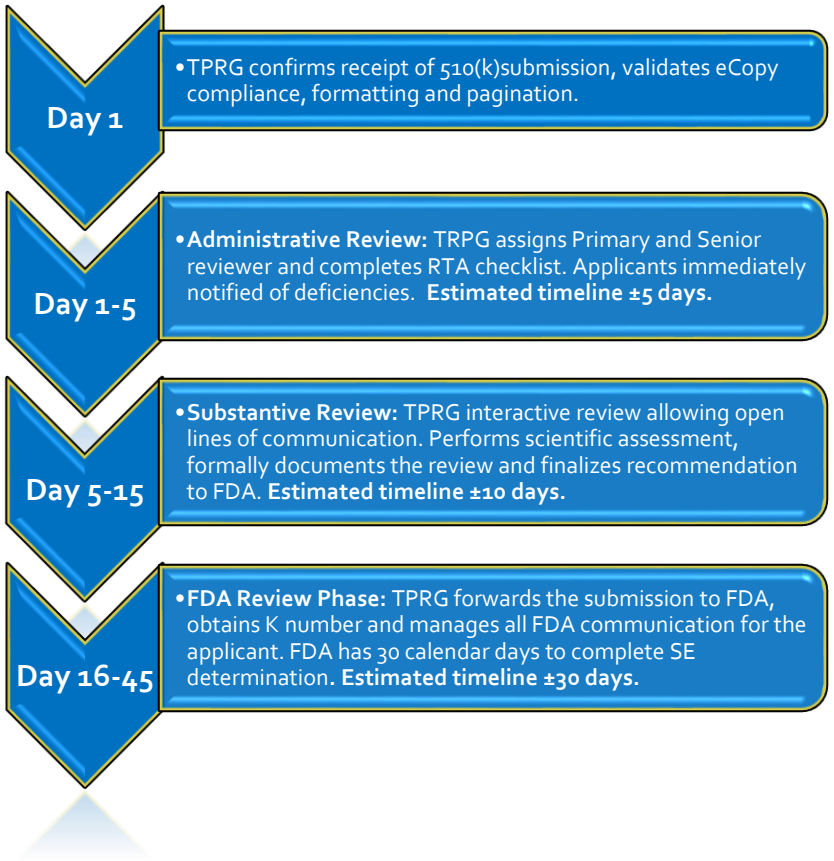
Day 2-10
- **Administrative Review:** TRPG assigns Primary and Senior reviewer and completes RTA checklist. Applicants immediately notified of deficiencies. **Estimated timeline ±10 days.**

Day 10-30
- **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

Special 510(k) Cycle Timeline

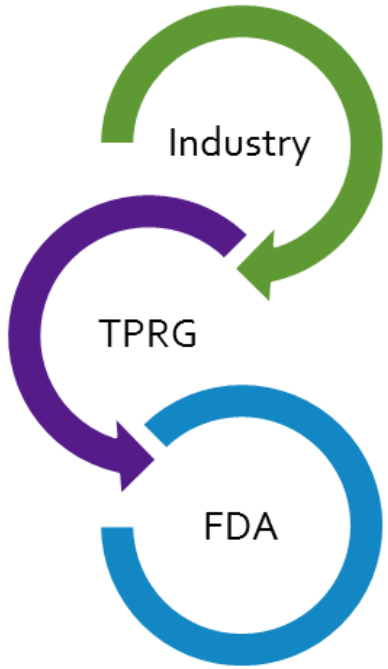


TPRG review capabilities include the review and substantial equivalence determination for **Special 510(k)** submissions.

* Requires applicant provide access to the predicate device submission

*45 Day Average

Capabilities and Client Advantages



FDA Branch Accreditations
Anesthesiology
Cardiovascular
Dental
Ear Nose & Throat
Gastroenterology
General & Plastic Surgery
General Hospital
Immunology
Neurology
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 FDA Office of Device Evaluation Divisions
- 14 Device Branches
- Over 1,200 Product Codes
- 23 Accredited Reviewers Available

Testimonials

" It was a pleasure working with TPRG! After using other Third Party Reviewers in the past we were skeptical of using the service again but were extremely pleased with the process and quick review time. We plan to use their service for future eligible submissions."

"International Device Company"

"I am thoroughly impressed by the excellent service that Third Party Review Group, LLC provides. Arteriocyte Medical Systems, Inc. utilized Third Party Review Group for a 510k submission to the Center for Devices and Radiological Health, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices. Third Party Group, LLC was able to facilitate a review and approval during a government shutdown clearly demonstrating their expertise, project management, and adherence to timelines. As a result of our partnership with Third Party Review Group, LLC, we were able to meet our goal of bringing our product to the marketplace in a timely fashion."

"Arteriocyte Medical Systems, Inc."

USA Headquarters
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041
Main: +1 973 379 2255

UK Headquarters
The Old Barrel Store
Draymans Lane
Marlow, Bucks SL72FF
Main: +44 1628 400687

"My experience with TPRG has exceeded both my expectations and previous experiences with third party reviewers. TPRG commits to review timelines, and they meet them. This helps reduce submission review time variability, which in turn helps me meet my commitments to my business. TPRG's staff is very professional, and the communication channels are always open. I appreciate their commitment to continuous improvement and the solicitation of feedback after the review process is complete. I will continue to use TPRG for my 510(k) reviews."

"Top 15 Global Medical Device Company"

"We were very satisfied with the review process. The review was conducted efficiently and TPRG was able to conduct a very comprehensive and thorough review within a very short turn time. We were also very impressed with the attention to details of the reviewers. Our assigned reviewers were very knowledgeable. During the initial review process, we were impressed by the level of detail of the initial response from TPRG. The level of detail on the questions asked especially on the Software section shows that all the reviewers are very knowledgeable on their respective areas. We were also impressed on the knowledge demonstrated by the lead reviewer on the overall review process, the sterilization section and that lead us to FDA clearance."

"Top 10 Global Medical Device Company"