

Combination Product Case Study

Product

- Combination product
- Ongoing sales

Issue

- Testing strategy pre-established, but not standards based
- Minimal combination product knowledge
- No knowledge of new performance testing standards

Resolution

- Review product testing needs, unique aspects of the product, unknowns and associated risks
- Review current/new standards and apply tests based on application
- Created, validated and executed test methods to meet specific needs for regulatory submissions

