



# RCA Case Study

Product  
Development

Regulatory 510(k) Analysis  
Product Cleaning/Disinfection

## Background

A global Fortune 500 company wanted to eliminate presterilization by ethylene oxide (EtO) of a family of medical devices - instead providing the customer with instructions for cleaning and disinfecting the product prior to use and in the event that the customer may choose to reuse the product. The elimination of EtO sterilization would result in a substantial reduction in the cost of manufacturing, due to eliminating the cost of the sterilization as well as enabling the use of lower cost packaging materials.

## Challenge

A suitable cleaning and disinfection process needed to be validated as safe and effective, and a regulatory analysis was needed to determine the need for any regulatory submissions.

## Approach

Regulatory Compliance Associates, Inc. (RCA) developed a test plan and coordinated testing that demonstrated a microbiological log reduction of greater than  $10^3$  using the proposed cleaning and disinfection process. Additionally, a formal regulatory analysis was conducted, evaluating the nature of the product application and relevant predicate device 510(k) filings to determine the necessity for filing a 510(k).

## Result

The regulatory analysis concluded that a 510(k) filing to clear the change with FDA was not required. Instead, a formal regulatory opinion and supporting validation testing was documented in the product Design History File. Due to not needing the 510(k), the project was completed under budget by over 60%, and the client realized a substantial product cost savings several months ahead of schedule.

## References

1. FDA Guidance Document, "Deciding When to Submit a 510(k) for a Change to an Existing Device", January 10, 1997
2. ISO 17664 – Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
3. FDA Guidance Document, "...Validation Data in 510(k)s for Preprocessed Single-Use Medical Devices", September 25, 2006