REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Regulatory 510(k) Analysis Development Product Cleaning / Disinfection

Client

Fortune 500 Medical Device Company.

Industry

Medical Device

Business Challenge

Developing a safe and effective process for cleaning and disinfecting products.

Background

TA global Fortune 500 company wanted to eliminate pre-sterilization 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.

RCA Approach

Regulatory Compliance Associates® Inc. developed a test plan and coordinated testing that demonstrated a microbiological log reduction of greater than 103 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).

Results

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 percent, and the client realized a substantial product cost savings several months ahead of schedule.

"The project was completed under budget by over 60% with substantial product savings, several months ahead of schedule."

References

1. U.S. Department of Health and Human Services, Food and Drug Administration, “Deciding When to Submit a 510(k) for a Change to an Existing Device, (K97-1)” January 10, 1997.

2. International Standards Organization, ISO Standard 17664: Sterilization of Medical Devices—Information to be provided by the manufacturer for processing of resterilizable medical devices. 2004.

3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, “Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices,” September 25, 2006.