**Sterilization validation**

*【参考指南“Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile”以及标准e.g., ANSI/AAMI/ISO 11135-1 or ISO 11134 or ISO 11137进行验证。*

*相关内容可以到FDA官网查询最新的指南，并确认最新的标准版本。*

*】*