Characterizing Simulated-Use Test Soils Used in Reprocessing Validations

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Biomarkers and the State of the Practice

The composition of the test soil plays an important role in soil selection. Most investigators use simulated-use soils that closely simulate the actual soil found in the body fluids of medical devices. The soil should be used with caution to prevent contamination of the medical device with other materials.

The recently published FDA guidance on this subject directs medical device manufacturers to use at least two biomarkers when validating the effectiveness of their cleaning instructions for reprocessing medical devices. The biomarkers should be selected and documented in the literature. For example, there are several means to detect and measure protein, carbohydrates, and metals.

In a laboratory setting, the starting composition of the soil contamination can be defined, as well as the use of any detection/quantification method after cleaning to compare the starting soil to determine a level of cleaning effectiveness. As enforced by the FDA guidance, the positive control can be determined by inoculating a defined volume of test soil on the device.