

Regulating Particles on Implantable Medical Devices



By

Christine M. Kielhorn, Ph.D.

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For the majority of medical devices, there is no regulatory standard governing the testing and limits of surface particulate contamination. However, there may be risks to a patient receiving a contaminated implantable device. We propose a general approach for testing implantable medical devices for particulates and setting limits for acceptable levels of particulate contamination for use by medical device manufacturers.

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