

Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

Frequently Asked Questions About Medical Devices

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Office of Good Clinical Practice
Office of Special Medical Programs, Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave., WO32-5129
Silver Spring, MD 20993-5129
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<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>

or

Division of Small Manufacturers, International, and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., WO66-4521
Silver Spring, MD 20993
Tel: 1-800-638-2041 or 301-796-7100
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Best regards,
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President, Clinical Device Group Inc

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