

40 C.F.R. § 610.30

General.

- (a) If the Administrator determines, by the criteria given in subpart B, that the claims made for a device are not supported by existing test data or other information, the Administrator will request the manufacturer to furnish additional information, and may design a test program to investigate those areas where claims appear to be erroneous or unsupported or where adverse effects due to use of the device are suspected.

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