**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Question
**Date:** Friday, September 01, 2017 2:43:00 PM
**Attachments:** [redacted]

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Good afternoon,

The HHS regulations at 42 CFR 110.10(a) define an "applicable device clinical trial" as "A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." (emphasis added) Trials which meet the definition of an applicable device clinical trial would be required to be registered on ClinicalTrials.gov.

See the regulations at https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-%20and-results-information-submission

You may also wish to review the NIH Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) at http://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

**Patrick J. McNeilly, Ph.D.**
*Senior Health Policy Analyst*

**Office of Good Clinical Practice**
**U.S. Food and Drug Administration**

**From:** [redacted]
**Sent:** Friday, September 01, 2017 12:52 PM
**To:** OC GCP Questions
**Subject:** Question

Hello,

We have a sponsor who states their class ll, low risk device for a 510K submission and does not require to be registered on clinicaltrials.gov, is that correct?

[redacted]