

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** FW: 21 CFR 56.109(c)  
**Date:** Wednesday, August 19, 2015 6:29:43 AM

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Hi [REDACTED] –

It is probably best to contact the Center for Devices (CDRH) directly as registry studies are handled differently in each Center.

For devices -- [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov) Phone: 1-800-638-2041

Kind regards,

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Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** [REDACTED]  
**Sent:** Tuesday, August 18, 2015 5:05 PM  
**To:** OC GCP Questions  
**Subject:** Re: 21 CFR 56.109(c)

Hi Doreen,

I am wondering about registry studies that are required as a result of a expedited access application for a device. In particular, are registry studies that do not require IDEs as per April 2015 Balancing Premarket And Postmarket Data Collection for devices subject to Premarket Approval, page 12, second paragraph, [There are no 21 CFR 812 investigational device exemption \(IDE\) requirements for the post approval confirmatory study, as long as the device is studied in accordance with its approved labeling, including indications for use.](#) Does this

Does this mean that 21 CFR 56 and 21 CFR 50 do not apply to these studies either since they apply to studies that require IDEs?

Thanks,  
[REDACTED]