

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Devices exempt from IDE Regulations
Date: Friday, September 26, 2014 11:50:18 AM
Importance: High

Good morning –

I reached out to the IDE staff for an answer to your question. Please see their response below.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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: Friday, September 26, 2014 11:31 AM
To: OC GCP Questions; [redacted]
Subject: RE: Devices exempt from IDE Regulations
Importance: High

Hi Doreen,

Based on the regulation 21CFR812.2, all clinical investigations of devices to **determine safety and effectiveness** should be regulated by FDA.

If the exempted device under 812.2(C) is investigated for **unapproved indications**, so long as the research concerns **safety and effectiveness determination**, the investigation should be under FDA oversight.

Please let me know if you have further questions.

Sec. 812.2 Applicability.

(a) *General*. This part applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in paragraph (c) of this section.

(c) *Exempted investigations*. This part, with the exception of 812.119, does not apply to investigations of the following categories of devices:

(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the

indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

Sofia

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From: [redacted]
Sent: Thursday, September 25, 2014 2:17 PM
To: OC GCP Questions
Subject: Devices exempt from IDE Regulations

Would a device which is exempt from the IDE regulations under 21 CFR 812.2(c) still be regulated by the FDA and the research under FDA oversight because the device is being used for an unapproved purpose? Or, if the data collected is not going to be used to support approval of the device or a new use for the device, would it no longer require FDA oversight?

Thank-you