From: [OC GCP Questions
To: [redacted] Questions
Cc: Kalb, Soma; Brown, Sheila (OGCP)
Subject: RE: Retrospective Chart Reviews: Are they FDA regulated?
Date: Friday, May 15, 2015 12:45:46 PM

Hi [redacted],
From the information provided in your email, this study is on-label for both products and is a retrospective chart review; this would exempt from 812. I'm not sure if the study would be subject to parts 50 and 56, since they are collecting safety and effectiveness data (infection and [redacted]).

If you would like to have FDA review the protocol and make a formal determination, please ask the study sponsor to submit a study risk determination per the instructions on pp 20-21 in the guidance, *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff*, which can be found at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf . The submission should be sent to CDRH at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have general questions about clinical trials, feel free to contact me or the Good Clinical Practice mailbox at gcp.questions@fda.hhs.gov .

For questions about device trials or for any questions about the pre-submission process, you may also contact Soma Kalb, Ph.D., Director of the IDE Program, at soma.kalb@fda.hhs.gov . She is copied on this email.

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Tuesday, May 12, 2015 4:26 PM
To: OC GCP Questions
Subject: Retrospective Chart Reviews: Are they FDA regulated?

Hello,
I am director of the IRB at my institution. We are reviewing a study in which hospital physican researchers want to do a retrospective chart review to look a infection and [redacted] for [redacted]. The [redacted] in question were FDA approved for this use. Our IRB wants to confirm that such a study
would not be considered a clinical investigation that would be regulated under parts 812, 50 and 56 or whether FDA would use enforcement discretion in applying those parts to rerospective review of data related to devices that were used according to their approved labels. We viewed this as more of a quality assurance study than a clinical investigation.
Thanks for your assistance.
[redacted]