From: OC GCP Questions
To: [redacted]
Subject: Customer Trial/Beta Test
Date: Wednesday, October 21, 2015 7:47:00 AM

Dear [redacted],
The determining factor for whether a device trial for an unapproved product falls under the IDE regulations (21 CFR 812) is whether or not safety and/or effectiveness data is being collected, not if it is exempt from 510(k) or PMA review. From the information provided, you indicate you plan to conduct a consumer preference study, and are not determining safety/effectiveness of your product. Studies for products regulated by FDA that are exempt from the IDE regulations should still have IRB review and informed consent (IC). If the study is being conducted for submission to FDA, then FDA's IRB and IC regulations need to be followed [21 CFR 56 and 50].

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Monday, October 19, 2015 3:36 PM
To: OC GCP Questions
Subject: Customer Trial/Beta Test

Hello,

I was referred to your department by **Eva Ellsworth,** Consumer Safety Officer at DICE. Below is my question for her:

Our company is in the final stages of development of a new [redacted]. We have been [redacted] as a contract manufacturer for over 10 years and follow 21 CFR Part 820 Quality System Regulation. Here is a link to our FDA registration information.
[redacted]

The device product code is [redacted], regulation number [redacted], and is exempt from 510(K) premarket notification requirements. We have an opportunity for a customer trial/beta test for our new [redacted]. Other than the standard paperwork that we are doing with our current process, is there any additional documentation required for a customer trial/beta test?

Her response to my inquiry was as follows:

"If you are doing preference testing or testing of a modification and if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk, your study is exempt from the requirement for an Investigational Device Exemption (IDE). An IDE allows an uncleared or unapproved device to be sent to clinical trial sites. If no IDE is required, you can use your standard paperwork. I don't know if a 510(k) exempt device is required to have an IDE for testing on humans. You may want to check with the Office of Good Clinical Practice."

Our goal for this beta test is for preference testing and is not determining safety or effectiveness. Does a 510(k) exempt device required to have an IDE for a customer trial? Thank you for your assistance and guidance.

Best regards,

[redacted]