From: OC GCP Questions
To:
Subject: NSR/SR designation
Date: Thursday, June 04, 2015 9:02:15 AM

Good morning –

You can contact someone in the Center for Devices (CDRH) directly. Please see their contact information below.

DICE@fda.hhs.gov
Manufacturer's assistance: 800-638-2041
Consumer assistance: 888-INFO-FDA
Questions about whether a product is subject to IDE regulations: call 301-796-5640

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, June 03, 2015 5:20 PM
To: OC GCP Questions
Subject: NSR/SR designation

To whom it may concern,

I was hoping that I might be able to get some direction as to who I might contact to discuss (non) significant risk designation for a medical device to be used in hospital study with IRB oversight. If you could please provide me with a phone number or email address of the appropriate party to speak to, I would greatly appreciate it.

Best,

[redacted]