

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

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: 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]