From: OC GCP Questions
To: [redacted]
Subject: Questions regarding device and drug study
Date: Wednesday, September 23, 2015 5:59:40 AM

Good morning --

You will need to contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov or the Office of Combination Products. Their web page and contact information are given below.

Combination Products

301-796-8930

Fax:301-847-8619

combination@fda.gov

Office of Combination Products

Food and Drug Administration

WO32, Hub/Mail Room #5129

10903 New Hampshire Avenue

Silver Spring, MD 20993

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.

-----Original Message-----
From: [redacted]
Sent: Tuesday, September 22, 2015 3:05 PM
To: OC GCP Questions
Subject: Questions regarding device and drug study

Good afternoon,

My name is [redacted], I am currently a cardiothoracic surgery resident at the [redacted]

. I have a question regarding a study that I would like undertake. The study is post operative atrial fibrillation in cardiac surgery in patients using amiodarone vs amiodarone combined with bi-atrial pacing. My question is regarding the device, Medtronic epicardial pacing wires which we put in all our cardiac patients for post-op pacing if needed. Since we will be using the pacing wires for a use that they have already been approved for by the FDA do I need to apply for an investigative device exemption? As well I will be applying for an investigative drug exemption for the use of amiodarone since it is used off label for atrial fibrillation. If I did need to apply for both a device and drug exemption would I apply for them separately? Or is there a way to apply for them together since they are going to be used in the same study?

Thank you for your time,

[redacted]