

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Bariatric Pacemaker
Date: Tuesday, April 15, 2014 2:41:17 PM

Good afternoon –

Your question should be sent to the Center for Devices (CDRH). Please feel free to call or email them directly.

CDRH –

Phone -1-800-638-2041

Phone -301-796-7100

Fax - 301-847-8149

dsmica@fda.hhs.gov

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: FYXUMXQ
Sent: Tuesday, April 15, 2014 2:10 PM
To: OC GCP Questions
Subject: Bariatric Pacemaker

I have a physician who currently has privileges at k for General Surgery and Bariatric Surgery. He has requested an additional non-core privilege of Bariatric Pacemaker placement for gastroparesis. I am researching this privilege and would like to know if any gastric pacemakers are currently approved for this procedure? If not, are any currently being tested?

I would appreciate any assistance/information you can provide.

Thank you,

k