FDA Questions for the Panel

Questions regarding the Reclassification Petition submitted by RS Medical:

The petitioner (RS Medical) has submitted a reclassification petition for a general non-invasive bone growth stimulator (BGS) device. The petition seeks reclassification from class III (premarket approval) to class II (special controls) for both Capacitive Coupling and Pulsed Electromagnetic Fields devices. The petition excludes invasive BGS, Combined Magnetic Field (CMF) BGS, and non-invasive ultrasound BGS.

1. In regards to the following devices which are proposed for reclassification, do you believe that the device description adequately describes and characterizes the devices? If not, what changes in the definitions or characterizations do you recommend?
    a. Capacitive Coupling
    b. Pulsed Electromagnetic Fields

2. In regards to the following devices which are proposed for reclassification, do you believe that the risks to health are adequately described? If not, what additional risks to health do you believe should be included?
    a. Capacitive Coupling
    b. Pulsed Electromagnetic Fields

3. Special controls have been proposed to address the risks to health identified for each of the above device configurations. Do you believe appropriate special controls have been identified to adequately address these risks to health? If not, what additional controls, if any, do you recommend to address these risks to health?

4. Device labeling has been cited as a control with which to address risks to health. The proposed labeling requirements are consistent with those generally found in current non-invasive BGS package labeling. This labeling generally includes device description, type of materials, indications for use, contraindications, adverse events, precautions, warnings, a listing of compatible components, and sterility information. What additional labeling, if any, do you recommend for Capacitive Coupling and Pulsed Electromagnetic Fields devices?

5. Do you believe the data presented in this petition supports the reclassification of:
    a. All non-invasive Capacitive Coupling BGS devices identified in this petition? If not, which types of non-invasive BGS devices do you believe are inappropriate for reclassification, and why (e.g., they have insufficient information and/or special controls)?
    b. All non-invasive Pulsed Electromagnetic Fields BGS devices identified in this petition? If not, which types of BGS devices do you believe are inappropriate for reclassification, and why (e.g., they have insufficient information and/or special controls)?

General Questions:

A general device type does not necessarily restrict the included devices to an identical or a single technology. Several devices, product areas, and indications for use have been excluded from this petition.

6. The proposed reclassification excludes the Combined Magnetic Fields (CMF) device. Please discuss if the risks to health associated with this device type are significantly different than those risks to health associated with the proposed general device type.

7. The proposed reclassification excludes the invasive bone growth stimulators (FDA product code LOE) and the non-invasive ultrasound bone growth stimulators (FDA product code LPQ). Please discuss if the risks to health associated with these product types are significantly different than those risks to health associated with the proposed general device type.

8. The proposed reclassification excludes indications for the treatment of congenital pseudoarthrosis and as an adjunct to cervical fusion surgery in patients at high risk for non-fusion. Please discuss if the risks to health associated with these indications for use are significantly different than those risks to health associated with the proposed general device indications for use.