

Date: August 9, 2005

To: Orthopaedic and Rehabilitation Devices Advisory Panel

From: Orthopaedic Devices Branch
Division of General, Restorative and Neurological Devices,
Office of Device Evaluation, Center for Devices and Radiological Health

RE: September 9, 2005 Orthopaedic and Rehabilitation Devices Advisory Panel Meeting:
Clinical Study Design for Devices Intended to Treat Mild to Moderate Lumbar
Degenerative Disease.

We are seeking your recommendations regarding clinical study design for devices intended to treat mild to moderate lumbar degenerative disease, i.e., interspinous process spacers, nucleus replacements, and pedicle screw-based systems. FDA plans to relay recommendations to industry so that they can conduct effective clinical trials for these device types.

This panel packet contains questions to consider during your review and discussion. These questions focus on:

- Defining an appropriate patient population for whom each type of device may be appropriate to study;
- Defining the most appropriate control group(s) to study as an appropriate comparison for each type of device;
- Defining the most appropriate clinically significant endpoints to evaluate subjects in these studies for each type of device; and
- Recommending alterations to traditional spinal study designs that may be warranted given the less invasive nature of many of these devices, as well as the mild to moderately affected patient population.

Your panel packet contains the following information:

1. A summary, including background information, description of the device types, and intended patient population;
2. A discussion of FDA issues and concerns;
3. The questions that you will be asked to address during the meeting; and
4. A representative sample of relevant literature.

For questions related to your participation in the meeting, local arrangements, meeting logistics, etc., call/email Jan Scudiero, the Executive Secretary for the Panel at (301) 594-2036 x176 or jls@cdrh.fda.gov.