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### Introduction letter to the Panel

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dear Panel Member,

The Division of General and Restorative Devices (DGRD) in Office of Device Evaluation (ODE) has been working with manufacturers during the development of computer controlled surgical systems for use in orthopedic procedures. We are having a public Panel meeting to discuss methods for studying these technologies. In the open public session of this meeting, you will be asked to address broad issues relating to data which may be useful in understanding and assessing this technology.

The following is a brief explanation of each section of your Panel package: The 1<sup>st</sup> section has FDA's questions on which we would like you to focus your comments. The 2<sup>nd</sup> section contains a brief literature summary and some literature references describing computer controlled surgical technologies and some published clinical experience with these devices.

If you have any additional questions about this panel meeting please contact Mr. Yung Pak or Mr. Neil Ogden at (301) 594-1307.

Sincerely,

A handwritten signature in black ink, appearing to read "Hany Demian", written over a horizontal line.

Mr. Hany Demian,  
Executive Secretary for  
Orthopedic and Rehabilitation  
Device Advisory Panel

## 1. FDA Panel questions

## FDA QUESTIONS TO PANEL MEMBERS

### (Open Session)

The Office of Device Evaluation has been working with industry to evaluate **computer-**assisted surgical devices in orthopedic use. Computer-assisted surgical technology has been described in the literature as noted in the articles provided in your panel package. Both FDA and industry are working together to design appropriate studies to evaluate the technology's safety and effectiveness.

1. Please discuss the types of preclinical data that would be important to evaluate this technology.
2. Please discuss important study endpoints to consider for the evaluation of these types of devices. Please discuss any longer term safety concerns that need to be addressed in study design.
3. Regarding surrogate endpoints for a computer-assisted surgical technology, are there quantitative and/or qualitative short term endpoints that could best capture an improvement in the procedure? For example, radiologic assessment, or other intraoperative assessments of technical success.
4. What longer term effectiveness endpoints (including clinical endpoints) would be important to consider in looking at risk-benefit for these products?