

Panel Questions

1. Please discuss each of the following proposed in this GDS:
 - a) The adequacy of the target composite endpoint criteria, and each individual component at the defined time point;
 - b) The necessity of other endpoints to be included in the endpoints and outcome targets for the devices proposed; and
 - c) The adequacy of the target sample size, delta, and confidence intervals for observed success are based on the proposed objective performance criteria at the defined time point presented in the GDS. If any are not adequate, discuss what options would be reasonable in terms of endpoints, sample size or any other parameters.

2. **Study duration**

Based on previous discussions about orthopedic implants, the Orthopaedic and Rehabilitation Devices Panel has indicated that long term follow up is preferred for orthopaedic implants. The benchmarks for success proposed in this document suggest achieving these at a one year point of reference. Based on the facts presented in the NIH consensus document and summaries provided by the Dartmouth Atlas of Musculoskeletal Health care, the outcomes for hip replacement vary according to the length of follow-up. Please comment on the duration of patient follow-up in the context of the proposed composite objective performance criteria for patient and study success presented in this document. Include a discussion of the time patients should be followed after treatment in order to establish durability of effect and safety for permanent hip implants

3. **Patient selection**

The success of any device is based on proper patient selection. Please discuss any inclusion and exclusion criteria that would be important to incorporate in any guidance. Include in this discussion, the diagnoses, recreational activities, work level, anatomical factors, medical/psychological co-morbidities and any other confounding factors that would affect the outcome of the patients receiving hip joint replacement. Include in your discussion any entry criteria related to endpoint assessment scales in terms of disability, pain, radiographic criteria, and/or quality of life. For example patients to be enrolled would have a maximum of 70 on the HHS, i.e., <70 for entry into the study for treatment.

4. **Outcome Measures**

There may be some disagreement in the orthopaedic scientific community over what constitutes a successful outcome, leaving nebulous definitions of endpoints which would correlate with prosthesis failure or success. Despite common acceptance, outcome assessment has been limited by the use of various outcome assessment tools that rely on the surgeon's assessment of pain and function. Many of these measures may not have been adequately characterized in terms of validity reliability and responsiveness to change. Conventionally used outcome measurements have not included any standardized patient-oriented evaluations of function, satisfaction or a global outcome measure. Please propose and discuss any new ideas for appropriate alternative outcome measures and/or surrogate endpoints to

predict success in patients who may be younger, healthier, heavier, and more active than those in the historical literature reviewed.

5. Post market studies

Long-term outcomes studies are not always possible, however, with a reduction in economic burden facilitated by a guidance, such as that proposed in this GDS, post market surveillance studies may be appropriate to evaluate specific questions regarding longer term safety or effectiveness. Please comment on the following:

- a) The types of questions a post market questions may be appropriate to address;
- b) If necessary, the duration of follow-up that would necessary to address the questions asked; and
- c) The amount and type of data that should be collected to answer the posed questions after device clearance or approval

6. Hip systems

The sponsor has included several different classifications of hip systems in the introduction to the document. These systems are general categories of systems which have been in use for several decades. Based on your experience and the experience in published literature, please comment on the types (classifications) of hip systems that would be amenable to the use of objective performance criteria and which are not.