

FDA Presentation

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Pre-Clinical Issues

1. The sponsor has provided a combination of engineering testing, biocompatibility testing, functional animal studies, device retrievals and analysis, radiographic follow up and clinical observations to address the degree of constraint, materials of articulation, and other design features of the Bryan Cervical Disc Prosthesis. Please discuss the testing, the data and the clinical observations regarding:

- device wear
- material and particulate reaction
- device expulsion or migration
- implant durability and reliability and
- sheath purpose and function.

Preservation of Motion

2. The sponsor has presented radiographic data to demonstrate preservation of motion at the index level in the patients receiving the investigational device. Motion at the index level did not correlate with clinical success

Further analysis has demonstrated that the motion, as measured by dynamic radiographs, was not significantly different at adjacent levels for the investigational device and for controls.

Please discuss how index level and adjacent level motion contribute to the effectiveness of the investigational device.

Labeling

3. Please discuss the adequacy of the device labeling.

What information related to mean operative time should be included in the labeling?

What information related to cervical levels should be included?

Safety

4. Under CFR 860.7(d)(1) , safety is defined as reasonable assurance, based on valid scientific evidence, that the probable benefits to health under conditions of the intended use, when accompanied by adequate directions for use and warnings against unsafe use, outweigh any probable risks.

Considering the adverse event rates for the subject device, please discuss whether the clinical data in the PMA provide reasonable assurance that the device is safe.

Efficacy

5. Please discuss whether the clinical data in the PMA provide reasonable assurance that the proposed device is effective.

Superiority

6. The sponsor has presented comparisons of the investigational and control procedures based on a variety of datasets (e.g., as randomized, as implanted). Please discuss whether these prespecified secondary analyses support the sponsor's claim that the investigational device is superior to the control procedure with respect to the overall success endpoint

NOTE TO PANELISTS: *FDA's inclusion of a question regarding a Post approval study should not be interpreted to mean that FDA has made a decision or is making a recommendation on the approvability of this PMA device. The presence of a post approval study plan or commitment does not in any way alter the requirements for premarket approval and a recommendation from the Panel on whether or not to approve a device must be based on the pre-market data. The pre-market data must reach the threshold for providing reasonable assurance of safety and effectiveness before the device can be found approvable and any post-approval study could be considered.*

Post-Approval Study

7. Please discuss the following issues related to a potential post-approval study (PAS):

Is it necessary to recruit new patients/physicians in the PAS or to use an alternative approach to evaluate the device's "real-world" performance after approval?

Is 7 year follow up appropriate for this device?

Post-Approval Study

Question continued from previous slide

7 . Please discuss the following issues related to a potential post-approval study (PAS):

Should treated level and adjacent level motion and the occurrence or progression of adjacent-segment disease be assessed in both groups in the PAS?

Should the rate of HO and kyphosis after Bryan Cervical Disc implantation be investigated in the PAS?