

Panel Questions

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1. Compare the mechanical properties of the Regen device and the mechanical properties of the referenced predicate devices as they relate to the ability of the devices to serve as a scaffold for tissue ingrowth in the parts of the body for which they are indicated. Please consider the following:
 - Are the devices able to withstand the mechanical forces present in the joint or other part of the body for which they are indicated sufficiently to achieve their intended purposes?
 - What is the impact on joint or other bodily function should the devices fail?

Panel Question

2. Discuss any issues related to fostering the growth of tissue by the ReGen device in the knee as compared to issues related to fostering the growth of tissue by the referenced predicate devices in the parts of the body for which they are indicated. Please consider the following:

- Histologic and clinical description of new tissue
- Effectiveness of the devices in achieving their labeled indications
- Risks associated with use of the devices for their labeled indications
- Timeline for tissue ingrowth

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3. Discuss any clinical issues related to use of the ReGen device in the knee, as compared to use of the referenced predicate devices for their cleared indications.

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4. Considering the data provided by ReGen on the CS device, the nature of the indication, for the reinforcement and repair of chronic soft tissue injuries, and your own experience, do you believe that ReGen has demonstrated that the CS device is at least as safe and effective as the predicate devices?

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5. Please comment on an indication of the device for the reinforcement and repair of acute soft tissue injuries.