ReGen is requesting clearance of the ReGen Collagen Scaffold (CS) for the following indication:

> for use in surgical procedures for the reinforcement and repair of chronic soft tissue injuries of the meniscus (one to three prior surgeries to the involved meniscus) where weakness exists. In repairing and reinforcing meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

FDA has not previously cleared a surgical mesh device for this specific indication. In its 510(k) submission, ReGen referenced several legally marketed surgical meshes used in orthopedics, thoracic, and general surgery as predicate devices (these are included in your panel pack).

In order to establish that a device with a new indication is substantially equivalent to a legally marketed predicate device, the 510(k) submission must include appropriate supporting data showing that the manufacturer has considered the consequences and effects the new use might have on the safety and effectiveness of the device. The 510(k) submission also must explain why the new indication does not affect the safety and effectiveness of the device when used as labeled. With respect to this 510(k), then, FDA must determine whether use of the device for the indication described above affects the safety and effectiveness of the device when used as labeled. FDA is requesting the assistance of this panel in evaluating the data submitted by ReGen in making this determination.

We request that you address the following issues:

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?

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

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.

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?

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