FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Voting Questions

11.2 Panel Voting Question

The following Indications for Use are proposed by the sponsor in the De Novo request:
"The intended for use of the NUsurface Meniscus Implant is to improve pain and function in the medial compartment of a knee in which the medial meniscus has been resected. The indication for use is in patients with:

--mild-to-moderate osteoarthritis,
--mild or greater knee pain, and
--cartilage present on the load bearing articular surfaces.

Each element needs confirmation from patient history, physical examination, radiographic imaging, and/or visual observation."

- Contraindication*: "Patients with extrusion of the medial meniscus 5mm or greater are contraindicated for the device."*
- Warning*: "Patients in which the height of the tibial spine is below 11mm are at greater risk of device related adverse events."*

Based on a consideration of the clinical information provided, do the probable benefits to health of the NUsurface Meniscus Implant outweigh the probable risks when used in patients in accordance with the proposed indications for use?