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510(k) Summary of Safety and Effectiveness

Trade Name: ADVANCE™ Tibial Component
Common Name: Metal-backed Tibial Component
Product Classification: II
Predicate Device: Insal/Burstein Modular Total Knee System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use

The ADVANCE™ Tibial Component is part of the ADVANCE™ Total Knee System, a total knee replacement system consisting of femoral, tibial, and patellar components. The ADVANCE™ Tibial Component is a modular two-piece component consisting of a metal tibial base and a plastic insert. The ADVANCE™ Tibial Component is intended to be used only with bone cement.

The ADVANCE™ Tibial Component is intended for tricompartmental or bicompartamental replacement of the knee for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions: 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis; 2) inflammatory degenerative joint disease including rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; 5) treatment of fractures that are unmanageable using other techniques.

Materials

The metallic tibial base component is manufactured from cobalt chrome alloy. The tibial insert components are manufactured from ultra high molecular weight polyethylene.

Testing Summary

- Submitted fatigue testing demonstrates that the ADVANCE™ Tibial Base Component was able to withstand test loading designed to simulate *in vivo* loading.
- Submitted femoral-tibial contact area testing demonstrates that the ADVANCE™ Tibial Component is more conforming (higher contact area) than independently published data for the predicate device.
- Submitted locking detail testing demonstrates that the ADVANCE™ Tibial Component lock detail integrity is comparable to other posterior stabilized knee systems available on the market.
- Submitted femoral-tibial constraint testing (anterior shear, posterior shear, medial shear, lateral shear, and rotation) demonstrates that the ADVANCE™ Tibial Component is expected to remain stable and resist displacement when subjected to appropriate physiological loads.
- Submitted ultra high molecular weight polyethylene (UHMWPE) properties demonstrate that the ADVANCE™ tibial insert polyethylene components should perform adequately.