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510(k) Summary

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Trade/Common Name: Tibial Tray Plug
Classification Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
Predicate Devices: Tibial Tray PMMA Plug, Wright Medical Technology, Inc.
MGII tibial tray plug, Zimmer, Inc.

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

Description

The Tibial Tray Plug is intended to be used with all the tibial bases that are available in the AXIOM™ Total Knee System. The purpose of the Tibial Tray Plug is to provide a filler for the screw holes to prevent extrusion of bone cement through the holes when the metal base is implanted without screw fixation. The Tibial Tray Plug will be machined from ultra high molecular weight polyethylene (UHMWPE) conforming to ASTM F 648. The one-piece design will be offered in two alternative slot styles, 4-slotted and 3-slotted.

The Tibial Tray Plug will be offered sterile in a pack of four for insertion into one or more of the four screw holes of the tibial base by the surgeon intraoperatively. The Tibial Tray Plug will also be available preassembled into the tibial tray. Tibial Tray Plugs are placed into the screw holes from the underside of the metal tibial base and snap fit snugly into place. If desired, the Tibial Tray Plug can be removed by using an instrument such as a hemostat to push the plug from the top of the base back through the screw hole.

Indications

The AXIOM™ Total Knee System is indicated for use in total knee arthroplasty 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; and
- 5) treatment of fractures that are unmanageable using other techniques.

Summary of differences

The Tibial Tray Plug is similar to either of the two predicate devices with respect to material, design, availability, and intended use. The only difference left between the Tibial Tray Plug and both predicate devices is the sterilization method. The predicate devices are sterilized with gamma radiation and the Tibial Tray Plug will be sterilized with ethylene oxide, both well accepted for achieving a sterility assurance level of 10^{-6} .

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