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510(k) SUMMARY

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In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a 510(k) Summary for the Sulzer Orthopedics Inc. Natural-Knee® II Revision Femoral Spacer Lugs.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, TX 78717 (512) 432-9687
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Knee joint femorotibial metal/polymer semi-constrained cemented prothesis, 21 CFR 888.3530.
Common/Usual Name:	Femoral Spacer Lugs
Trade/Proprietary:	Natural-Knee® II Revision Femoral Spacer Lugs

Product Description/Substantial Equivalence:

The Natural-Knee II Revision Femoral Spacer Lug is in effect a bolt. The threaded portion of the lug screws into blind holes on the inner box of the Natural-Knee II Revision Femoral Component. A large hexagonal head allows the lug to be tightened into place. When used with a femoral spacer, the lug holds the spacer component firmly in place. When used without the spacer, the lug provides medial-lateral stability similar to that of conventionally cast or machined pegs usually found on the inner box of most femoral components.

Analysis of the lug shear strength indicated that the component should survive physiologic loading.

The Natural-Knee II Revision Femoral Spacer Lugs are similar to the Smith & Nephew Richards Genesis and Tricon-M FlexLok Pegs, the Smith & Nephew Richards Genesis Modular Femoral Lugs, and the Howmedica Duracon Modular Femoral Pegs.

The Natural-Knee II Revision Femoral Spacer Lugs are intended for cemented use with the previously cleared Natural-Knee II Revision Femoral Component and associated components (e.g., tibial, patellar, etc.) in the treatment of:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Correctable valgus-varus deformity and moderate flexion contracture.
3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.
4. Revision of previously failed knee arthroplasty.