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**Summary of Safety and Effectiveness
Cobalt-Chromium-Molybdenum Alloy Femoral Heads
with *Co-Nidium*TM Surface Hardening Process**

- Submitted by:

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- Date:

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- Trade Name:

Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy Femoral Heads with
Co-Nidium Surface Hardening Process

- Classification Name:

Hip Joint Metal/Polymer Semiconstrained Cemented Prosthesis

- Predicate Devices:

- Harris/Galante Porous Total Hip
- Enhanced Modular Austin Moore Hip Prosthesis
- HG *MultiLock*TM Hip Prosthesis With *Ti-Nidium*[®] Surface Hardening Process
- *MG II*[®] Total Knee System with *Ti-Nidium* Surface Hardening Process



- Device Description

The design of the femoral heads includes a spherical head portion that is highly polished and processed with the *Co-Nidium* surface treatment. Femoral heads for total hip arthroplasty procedures are available in diameters from 22 to 32 mm with varying neck lengths. Femoral heads for hemi-hip arthroplasty procedures are available in 38 to 63 mm outer diameters. The femoral heads include a tapered portion that fits securely onto a modular femoral stem component.

- Intended Use

Femoral heads are single-use devices that are mated via a press-fit tapered neck with titanium or cobalt-chrome alloy femoral stems in total and hemi-hip arthroplasty procedures.

- Performance Data

Wear testing demonstrated improved abrasive wear resistance when compared to the predicate device. Corrosion testing demonstrated that the breakdown potential of the alloy material is not changed by surface hardening. Fatigue testing indicated that the fatigue strength of the nitrided alloy is higher than the fatigue strength of currently marketed devices. Dimensional analysis and coefficient of friction data showed no change for the nitrided femoral heads. Microhardness and ESCA data exhibited higher hardness and depth of hardening when compared to the predicate device.

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