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K963206

**Summary of Safety and Effectiveness Data
for the S-ROM Hip System - Locking Plug**

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Name of Device _____

Proprietary Name: S-ROM Hip System - Locking Plug
Common Name: Locking Plug
Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II by 21 CFR § 888.3350
Product Code No.: 87JDI
Owner/Operator No.: 9001269

Device Classification _____

This device has been placed in Class II for Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR § 888.3350.

Statement of Substantial Equivalence _____

The S-ROM Hip System - Locking Plug is substantially equivalent to the Locking Pin currently marketed in the United States under both #K870271 and K924492.

The subject device is composed of the same material as the Locking Pin (Ti-6Al-4V Titanium Alloy). Further, the intended use, design, and manufacture of the Locking Plug are substantially equivalent to the currently distributed Locking Pin. Additionally, the packaging and method of sterilization utilized for the Locking Plug are the same as those used for the Locking Pin.

Indications for Use

The S-ROM Hip System - Locking Plug has the same indications for use as the S-ROM Hip System - Locking Pin. They are both indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from:

1. rheumatoid arthritis,
2. osteoarthritis,
3. post-traumatic arthritis,
4. collagen disorders,
5. avascular necrosis, and
6. nonunion of femoral fractures.

Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with:

7. congenital hip dysplasia,
8. *protrusio acetabuli*,
9. slipped capital femoral epiphysis,
10. and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Physical Description

The Locking Plug consists of a head and body. The head has both internal threading and external serrations (barbs). The internal threading allows attachment of the insertion tool to the Locking Plug. The body is cylindrical with an external lip. Both the external serrations of the head and the lip of the Locking Plug body aid in resisting disengagement of the Locking Plug from the shell/liner assembly. The Locking Plug is available in both 3.5 mm and 5.0 mm sizes.