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K962101

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for  
Zweymueller SL Femoral Hip Stem**

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 Zweymueller SL Femoral Hip Stem.

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**Proprietary name** Zweymueller SL Femoral Hip Stem

**Common Name:** Hip Prosthesis

**Classification name:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353).

**Predicate Devices:** The features employed by the Zweymueller SL Femoral Hip Stem are substantially equivalent to the features employed by the following predicate legally marketed devices:

Zweymueller-SL Hip Prosthesis, Sulzer Orthopedics Limited;  
and  
SL-Plus; Plus Endoprothetik.

**Device Description:** The Zweymueller SL Femoral Hip Stem employs a Sulzer 12/14 configured trunnion for attachment to femoral heads, including BioloX ceramic heads, featuring a Sulzer 12/14 configured bore. The BioloX heads have been determined substantially equivalent by the FDA via

510(k) number K892644. The Biolox ceramic heads are available in two sizes (28mm and 32mm outer diameters (OD)).

The Zweymueller SL Femoral Hip Stem is a line extension of an existing legally marketed SOL's Zweymueller-SL Hip Prosthesis which has previously been determined substantially equivalent by the FDA via 510(k) #K871453. The Zweymueller SL Femoral Hip Stem is identical in design to the predicate Zweymueller-SL Hip Prosthesis except for the following:

- \* The Zweymueller SL Femoral Hip Stem is provided sterile; and
- \* The Zweymueller SL Femoral Hip Stem is available in sizes 01 and 0 in addition to sizes 1 through 12.

The Zweymueller SL Femoral Hip Stem is designed as a conical straight stem with a rectangular cross section to ensure rotational stability. The proximal portion of the hip stem employs an extraction hole to facilitate removal of the stem in revision cases. The widened proximal geometry of the Zweymueller SL Femoral Hip Stem reduces stresses due to compressive and torsional forces by allowing forces to be transmitted over a larger area ( $\text{Stress} = \text{Force}/\text{Area}$ ). The proximal/lateral portion of the hip stem employs four holes for optional use with a cerclage wire to provide enhanced fixation of the hip stem to the greater trochanter.

The entire stem below the neck of the hip stem is grit blasted to provide enhanced fixation in both cemented and cementless total hip arthroplasties. In a cemented application, the grit blasted surface provides greater cement interdigitation with bone cement. In a press-fit or cementless application, the grit blasted surfaces provide an enhanced bone/prosthesis interface.

The distal tip of the Zweymueller SL Femoral Hip Stem is of pyramidal shape and is rounded off at the transition to the shaft. This facilitates transmission of load to the distal cortical bone.

**Intended Use:**

The Zweymueller SL Femoral Hip Stem is intended to replace the anatomy of the femur in cases of total hip replacement. In addition, the Zweymueller SL Femoral Hip Stem is intended to be intraoperatively assembled to the commercially available Sulzer Orthopedics Limited (SOL) or Intermedics Orthopedics, Inc. (IOI) femoral bearing heads.

The general indications associated with the use of Zweymueller SL

2. Fracture or avascular necrosis.
3. Conditions consequent to earlier operations such as joint reconstruction (Osteotomy), arthrodesis, hemi-arthroplasty, or total hip replacement (THP), total knee replacement, as well as operations on shoulder and elbow joints, and spinal surgery.

**Summary of  
Technological  
Characteristics:**

A side by side tabular comparison of the characteristics of the Zweymueller SL Femoral Hip Stem to those of the currently marketed IOI and competitive devices follows:

<b>Characteristics</b>	<b>Subject Device</b>  <b>Zweymueller SL Femoral Hip Stem</b>	<b>Predicate Devices</b>	
		<b>Zweymueller-SL Hip Prosthesis</b>	<b>SL-Plus</b>
Manufacturer	Sulzer Orthopedics Limited	Sulzer Orthopedics Limited	Plus Endoprothetik.
510(k) No.	-	K871453	K930963
Application	Cementless	Cementless	Cementless
Material	Titanium Alloy	Titanium Alloy	Unknown to IOI
Rectangular cross-section	Yes	Yes	Yes
Holes on the lateral side	Yes	Yes	Yes
Pyramidal shaped distal tip	Yes	Yes	Yes
Sizes	01, 0, and 1 - 12	1 - 12	Unknown to IOI