K960678

510(k) Premarket Notification
Summary of Safety and Effectiveness
for
Burch/Schneider Reinforcement Cage

MAY - 3 1996

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 Burch/Schneider Reinforcement Cage.

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Proprietary name Burch/Schneider Reinforcement Cage

Common Name: Acetabular reinforcement cage

Classification name: Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented (21CFR 888.3350). Class 2

Predicate Devices: The features employed by Burch/Schneider Reinforcement Cage are substantially equivalent to the features employed by the following predicate legally marketed devices:

- Preamendment H.B. Burch Anti-Protrusio Reinforcement cage: Sulzer Orthopedics Limited (Preamendment Status)
- Acetabular Roof Reinforcement Ring: Sulzer Orthopedics Limited (510(k) number K953578)
- Anti-Protrusio Reinforcement cage: Depuy Inc. (510(k) number unknown to IOI).

Device Description: The Burch/Schneider Reinforcement Cage is a modified version of the preamendment H.B. Burch Anti-Protrusio Reinforcement Cage, manufactured by Protek AG (now consolidated into Sulzer

Orthopedics Limited), that has been in commercial distribution in the United States prior to 1976.

The Burch/Schneider Reinforcement Cage will be manufactured from either stainless steel (AISI 316L) or commercially pure (CP) Titanium (International Organization for Standards (ISO) 5832-2). The design of the Burch/Schneider Reinforcement Cage include the following:

- a dome area with a dome hole and screwholes,
- a superior flange employing screwholes for the optional attachment to the ilium,
- an inferior flange employing screwholes for the optional attachment to the ischium,
- available in thickness of 2.0 (+0.0, -0.3)mm

Intended Use:

The Burch/Schneider Reinforcement Cage is intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency. In addition, the Burch/Schneider Reinforcement Cage, like the predicate devices, is intended to provide support for an all polyethylene acetabular implant in a cemented application.

Diagnostic indications for use of this device include, but are not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery.

The general indications associated with the use of Burch/Schneider Reinforcement Cage in total hip arthroplasty include:

1. Advanced joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis,

2. Fracture or avascular necrosis of the femoral head,

3. Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty and total hip replacement.

Summary of Technological Characteristics:

Substantial equivalence determination for the Burch/Schneider Reinforcement Cage is based upon the comparison of the subject device to the following legally marketed predicate Sulzer Orthopedics Limited and competitive devices:

- Preamendment H.B. Burch Anti-Protrusio Reinforcement Cage: Sulzer Orthopedics Limited (Preamendment Status)

- Acetabular Roof Reinforcement Ring: Sulzer Orthopedics Limited (510(k) number K953578)
- Anti-Protrusio Reinforcement cage: Depuy Inc. (510(k) number unknown to IOI)

The characteristics of the Burch/Schneider Reinforcement Cage, either alone or in combination, are substantially equivalent to the aforementioned predicate devices in terms of materials, intended use, and design characteristics. A side by side tabular comparison of the characteristics of the Burch/Schneider Reinforcement Cage to those of the predicate devices follows:

Characteristics	Subject Device	Predicate Devices		
	Burch/Schneider Reinforcement Cage	**H.B. Burch Anti-Protrusio Reinforcement Cage**	**Anti-Protrusio Reinforcement Cage**	**Acetabular Roof Reinforcement Ring**
Manufacturer	Sulzer Orthopedics Limited	Sulzer Orthopedics Limited	Depuy Inc.	Sulzer Orthopedics Limited
510(k) No.	-	Preamendment	Unknown to IOI	K953578
Application	Cemented	Cemented	Cemented	Cemented
Material	Stainless Steel or CP Titanium	Stainless Steel	Stainless Steel	CP Titanium
Superior Flange	Yes	Yes	Yes	No
Inferior Flange	Yes	Yes	Yes	No
Screwholes	Yes	Yes	Yes	Yes
Sterile	Yes	No	Unknown to IOI	Yes
Sizes	44 and 50mm Left/Right	44 and 50mm Left/Right	44 and 50mm Left/Right	Diameters 36 - 58mm (2mm Increments)