

K962190

OCT 28 1996

**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Patellofemoral Joint Prosthesis**

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 Patellofemoral Joint Prosthesis.

Submitter: Intermedics Orthopedics, Inc. (IOI)
9900 Spectrum Drive
Austin, Texas, 78717
Tel.: (512) 432-9900
Fax: (512) 432-9291

Contact Person: *Regarding this submission:*
Name: Sam Mirza
Tel.: 512-432-9751
Fax: 512-432-9291

Official Correspondent
Name: Jacquelyn Hughes
Tel.: 512-432-9687
Fax.: 512-432-9291

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Proprietary name Patellofemoral Joint Prosthesis

Common Name: Patellofemoral Joint Prosthesis

Classification name: Knee Joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR 888.3540, Class III, 87KRR

Predicate Devices: The features employed by the Patellofemoral Joint Prosthesis are substantially equivalent to the features employed by the following predicate legally marketed devices:

- ▶ Bechtol Patello-Femoral Joint Replacement; Smith and Nephew Richards, Inc. (Preamendment Status);
- ▶ Type I Femoral Component; Smith and Nephew Richards, Inc. (Preamendment Status);
- ▶ Type II Femoral Component; Smith and Nephew Richards, Inc. (Preamendment Status);

- ▶ Lubinus Total Patella Glide Femoral Component; Waldemar Link (510(k) number or Preamendment Status unknown to IOI).

Device Description:

The design of the Patellofemoral Joint Prosthesis closely replicates the anatomic features of the patellar groove on a femur. In addition, the design of the highly polished concave gliding anterior surface of the Patellofemoral Joint Prosthesis is identical to the proximal anterior surface of the articulating geometry of the Natural Knee II System's femoral component which has been determined substantially equivalent by the FDA via 510(k) K936159. The highly polished concave gliding surface of the Patellofemoral Joint Prosthesis complements the design of the articulating geometry of the IOI's patella components for optimal patellar tracking.

The posterior surface of the Patellofemoral Joint Prosthesis employs two fixation pegs for enhanced stability of the prosthesis when cemented into the femur. In addition, the posterior surface of the Patellofemoral Joint Prosthesis employs a grit blasted roughened surface to facilitate interdigitation with bone cement. The roughness of the grit blasted surface ranges from 175 - 225 μ inch.

The Patellofemoral Joint Prosthesis is an asymmetrically designed component and, therefore, is available in both left and right configurations.

Intended Use:

The general indications associated with the use of Patellofemoral Joint Prosthesis in patellofemoral arthroplasty include:

1. Patients with osteoarthritis in the distal femur and patella.
2. Patients with a history of patellar dislocation or patellar fracture.
3. Those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

**Summary of
Technological
Characteristics:**

A side by side tabular comparison of the characteristics of the Patellofemoral Joint Prosthesis to those of the currently marketed IOI and competitive devices follows:

Characteristics	Subject Device	Medicare Codes			
	Patello-femoral Joint Prosthesis	Rechtal Patello-femoral Joint	Type I Patellar Component	Type II Patellar Component	Waldemar Patellar Prosthesis
Manufacturer	Intermedics Orthopedics, Inc.	Smith and Nephew Richards, Inc.	Smith and Nephew Richards, Inc.	Smith and Nephew Richards, Inc.	Waldemar Link
510(k) No.	-	Preamend.	Preamend.	Preamend.	Preamend. or 510(k) status unknown
Application	Cemented	Cemented	Cemented	Cemented	Cemented
Material	Cast CoCr Alloy	Cast CoCr Alloy / Stainless Steel	Cast CoCr Alloy / Stainless Steel	Cast CoCr Alloy / Stainless Steel	Cast CoCr Alloy
Concave	Yes	Yes	Yes	Yes	Yes
Fixation pegs	Two	Three	One	Three	Three
Asymmetric	Yes	No	No	No	Yes