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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 Summary of Safety and Effectiveness for the Wägner Revision Stem.

Submitter:	Intermedics Orthopedics, Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9687
Date:	February 9, 1996
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21CFR 888.3353
Common/Usual Name:	Femoral component
Trade/Proprietary:	Wägner Revision Stem

PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE:

The Wägner Revision Stem incorporates a circular cross-section with eight equally spaced conical anchorage ribs (or flutes) which run the entire length of the stem. This device is intended for cementless application where primary fixation occurs predominantly in the distal region and is primarily used in clinical situations where there are deficiencies in the proximal femur due to extensive bone resorption and/or damage in the prosthetic bed.

Currently, the Wägner Revision Stem is offered in four stem lengths (190, 225, 265 and 305mm) with distal diameters ranging from 14-20mm, 14-22mm, and 14-25mm (in 1mm increments) for the 190, 225, and 265/305mm lengths respectively. The number of size offerings is being increased to include a stem length of 345mm with distal diameters of 14-25mm (1mm increments) and a stem length of 385mm with distal diameters of 14-25mm (1mm increments).

The additional sizes are identical in configuration to the original Wägner Stems, but have been designed in proportion to the sizes already available. Static and dynamic testing were performed, verifying that the additional sizes exhibit sufficient strength for clinical use.

The modified Wägner Revision Stem is substantially equivalent to the Müller Type Proximal Femur marketed by Howmedica and the Proximal Third Femoral Prosthesis marketed by DePuy.