AUG 28 1996

510(k) SUMMARY

K962224

June 7, 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 Intermedics Orthopedics, Inc. Select® Shoulder Concentric Humeral Heads.

Submitter:	Intermedics Orthopedics, Inc. 9900 Spectrum Drive Austin, TX 78717 (512) 432-9900
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	No formal classification has been estabished for humeral head components.
Common/Usual Name:	Humeral Head Components
Trade/Proprietary:	Select® Shoulder Concentric Humeral Heads

Product Description/Substantial Equivalence:

The Select Shoulder Humeral Heads are metallic components manufactured from wrought cobalt chrome alloy (CoCrMo). The heads, once impacted onto one of the Select Shoulder humeral stems, are designed to articulate with the normal human glenoid or with a replacement all-poly glenoid component. The humeral heads feature a female taper which allows for attachment to the male taper of the Intermedics Orthopedics Select Shoulder Humeral Stems. The heads are available in a variety of heights and diameters. The humeral heads are designed for use with Intermedics Orthopedics Humeral Stems and/or glenoid components in a variety of sizes for increased stability of the glenohumeral joint.

Testing indicated that the pulloff strengths for the Select Shoulder Humeral Heads were comparable to currently marketed devices. Contact area testing indicated that the standard heads provide adequate contact area at various levels of abduction.

The Select Shoulder CoCr Humeral Heads are similar to those of the Depuy Global Total Shoulder System, the Biomet Bio-Modular Total Shoulder, the Zimmer Fenlin Total Shoulder, the Kirschner/Biomet Modular Shoulder System, the 3M/Orthomet Modular Neer II Shoulder System, and the Encore Foundation Shoulder System.