

FEB - 6 1997



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Date: February 6, 1996

510(k) SUMMARY

Trade/Proprietary Name: **Metallic Spherical CMC Implant**
Common Name: **Carpometacarpal (CMC) implant**
Product Nomenclature: **Prosthesis, wrist, carpal trapezium**
Classification: **Class II**
Predicate Device: **Swanson Titanium Condylar Implant**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use

The Metallic Spherical CMC Implant is intended to be used as an adjunct to resection arthroplasty of the carpometacarpal (CMC) joint in cases of degenerative arthritis or post-traumatic arthritis limited to that joint. It acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities. The implant will rest in a spherical cavity created by two hemispherical shapes in the trapezium and the first metacarpal. The implant will articulate directly on bone.

Use of the CMC Implant may be considered in cases of isolated carpometacarpal joint involvement from either degenerative or post-traumatic arthritis presenting:

- ▶ Localized pain and palpable crepitation during circumduction movement with axial compression of involved thumb ("grind test").
- ▶ Decreased motion, normal pinch and grip strength.
- ▶ X-ray evidence of arthritic changes and/or subluxation of the carpometacarpal joint.
- ▶ Associated unstable, stiff, or painful distal joints.

The Metallic Spherical CMC Implant is made from cobalt chrome alloy.

Substantial Equivalence

The Metallic Spherical CMC Implant is substantially equivalent to the Swanson Titanium Condylar Implant

Testing

The Metallic Spherical CMC Implant demonstrates acceptable material strength.

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