510(k) Summary

K964472

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Device Name: BIOPRO Cobalt Trapeziometacarpal Replacement

Classification: The FDA has not yet created a classification for this type of device.

Predicate Device: Swanson Titanium Condylar Implant (K864488)

The BIOPRO Cobalt Trapeziometacarpal Replacement is a one-piece resurfacing component for the basal thumb joint. It has an anatomically configured tri-flanged stem that fits into the medullary canal at the proximal end of the first metacarpal. This tri-flanged configuration allows for compaction of bone around the implant to provide stable fixation and to prevent rotation of the device. The head is spherical and extends just beyond a hemisphere, slightly medialized on the stem and is at a 20° varus angle to the stem to properly space the joint and allow for sufficient range of motion. The trapezium is resurfaced to contain the head of the implant and this resurfacing is continued into the second metacarpal. Resurfacing the second metacarpal prevents impingement of the implant against that bone and decreases the possibility of dislocation of the joint.

The BIOPRO Cobalt Trapeziometacarpal Replacement is intended to resurface the joint in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post fracture deformation or bone loss which present themselves as either a painful, instable thumb or a thumb with limited range of motion. These indications are the same as those for the predicate device, the Swanson Titanium Condylar Implant (K864488). The other similarities, and also the differences, between the subject device and the predicate device include their functions, materials and shapes. The components function the same; they both resurface the joint to provide pain relief and increase motion in the joint. Both components have a hemispherical head, however the ratio of head height to head diameter is slightly larger for the Swanson device than for the BIOPRO component. Also, while the head of the Swanson device is cylindrical below the hemisphere, the BIOPRO head continues the spherical radius to the edge of the head to increase the range of motion of the joint. Both devices' stems are intended to prevent rotation; however, their cross-sections are different. The Swanson device has a square cross-section and the BIOPRO device has a tri-flanged cross-section. The only other difference between the devices is the material. The BIOPRO component is manufactured from cast Cobalt Chrome (to ASTM F75) while the Swanson device

is manufactured from unalloyed titanium (to ASTM F 67). The use of cobalt as opposed to titanium allows for casting of the device. Also, cobalt chrome is not as soft a material as titanium which better suits the metal for use as an articulating surface.