K962514

510(K) SUMMARY

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Submitter: BIOPRO
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Device Name: BIOPRO Ceramic TARA Femoral Resurfacing Component
BIOPRO Ceramic TARA

Classification: Hip Joint metal/polymer, semi-constrained resurfacing component

Predicate Device: BIOPRO TARA Femoral Articular Replacement (K89604) for function and the BIOPRO Ziralloy Modular Femoral Head (K912641) and the BIOPRO Hemi-Endo Modular Ceramic Head (K954768 and K953045) for Material

The BIOPRO Ceramic TARA is a modular femoral resurfacing component that may be used as either a hemi-arthroplasty or with an acetabular component as a total arthroplasty. The inner surface of the head is cylindrical with a female taper at the deepest portion. The femoral head is surgically remodeled to fit the implant head. This shape of the remodeled femoral head allows for compressive forces to exist at the bone/implant interface and, therefore, provide stable support for the implant. The stem is designed to guide the head into proper position on the bone. Once the implant is in place, the stem is not intended to perform any functions. The ceramic head articulates against either the intact or an artificial acetabulum and is intended to provide normal mechanical aspects of the joint and physiological transmission of stresses to the proximal femoral bone.

The stem is manufactured from cobalt chrome to ASTM F-799. The head is manufactured from Zirconia ceramic that has been in use for total hip system components since November 1991, (K912641), (K954768), and a hemi-arthroplasty (K953045) since September 1995. Ceramic, especially transformation Toughened Zirconia (TTZ) was chosen as the material for the head for several reasons. First, using ceramic greatly improves the surface finish of the implant over its metal counterparts. The superior wear properties of ceramic against polyethylene are discussed in an article of the *Journal of Biomedical Materials Research*[1]. Also, Zirconias are superior to Alumina in strength and toughness[2]. Then, among Zirconias, testing performed by Drummond, et al, at the University of Chicago[3], has demonstrated the best choice for minimal loss of structural integrity is the TTZ. This data has also been substantiated by Australian Researchers[4].

The Ceramic TARA is intended for single use with cement fixation. It is indicated for degenerative arthritis, rheumatoid arthritis, and avascular necrosis. It may be used as a hemi-arthroplasty for those hips in which the concentricity and supportive bone structure of the

acetabulum are essentially normal and in which the selection of implant size provides a reasonably precise articulation. These indications are the same as those for the predicate device to which the current device is being compared.

The main differences between the predicate TARA device and the submitted device are the materials and the modularity. The modularity is necessitated by the use of ceramic. However, the modularity should not affect the function of the device, since the stem is only intended to the direct the implant into position. The head performs the mechanical function in the joint and its configuration is the same as that of the predicate device. The material change improves the surface finish of the subject device as compared to the predicate device. The material change improves the surface finish of the subject device as compared to the predicate device. As stated earlier, this greater surface finish gives the ceramic superior wear properties against polyethylene over metal.

NOTES

1. Praveen Kumar et al., "Low Wear Rate UHMWPE Against Zirconia Ceramic (Y-PSZ) in Comparison to Alumina Ceramic and SUS 316L Alloy", *Journal of Biomedical Materials Research* 25 (1991): 813-828.

2. James L. Drummond and John W. Lenke, "In Vivo and In Vitro Aging of Dense Alumina", *Advanced Ceramic Materials* 3, no. 2 (1988): 159

3. James L. Drummond, "Aging Study of Magnesia Stabilized Zirconia", Presented at the Third International Symposium on Ceramics in Medicine, Terre Haute, Indiana, November 18-20, 1990.

4. R.C. Garvie, C. Urbani, and J.C. McNeuer, "Biocompatibility of Magnesia-Partially Stabilized Zirconia (MG-PSZ) Ceramics," *Journal of Materials Science* 19 (1984): 3224-3228.