

## SECTION III

### CFR CLASSIFICATION OF METAL/POLYMER CONSTRAINED HIPS

#### A. Current CFR Classification of Metal/Polymer Constrained Hip Prosthesis

888.3310 Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

##### (a) Identification

A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is intended for use with or without bone cement (888.3027). This device is not intended for biologic fixation.

##### (b) Classification

Class III

#### B. Requested Reclassification

Since the only component of the device requiring reclassification is the constrained polymer acetabular insert, this petition offers the following proposal. Please note that modifications of the original classification appear in *italics*.

888.3310 Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

##### (a) Identification

A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene *with or without a metal shell made of alloys such as cobalt-chromium-molybdenum and titanium alloys*. This generic type of device is intended for use with or without bone cement (888.3027).

##### (b) Classification

Class II

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