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[Confirmation Copy of Comments Submitted Electronically]

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99P-1864
Orthopedic and Rehabilitation Devices: Reclassification of the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

To Whom It May Concern:

On behalf of a client, we respectfully submit these comments to the above-referenced docket to urge FDA **not** to reclassify the product type Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis (to be referred to throughout the rest of the document as the Constrained Liner) from Class III to Class II. Our client believes that such a reclassification would create serious risks to patients because the proposed special controls that would be applicable under reclassification are inadequate to protect against certain type(s) of failures, specifically shell-bone interface failures, that may be seen clinically with these highly constrained devices. Because FDA's notice of proposed reclassification failed to adequately consider the risks associated with device failure at the shell-bone interface,) putting, patients at risk. We respectfully urge the agency not to reclassify these devices unless and until this significant risk has been fully evaluated and adequately addressed by appropriate special controls. However, based on extensive experience with these devices, our

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client believes that this risk can only be addressed through the clinical testing necessary for approval of such devices under a Premarket Application (PMA).

At the Food and Drug Administration Orthopaedic Panel Meeting held on June 9-10, 1997, where Premarket Approval Applications for two constrained liners were discussed, and again at the Orthopaedic Panel meeting held on November 4, 1999 where the reclassification petition was discussed, panel members were quite concerned with the forces required for the device to fail, and also concerned with the interfaces where the device fails. A portion of the discussion centered on the importance that the failure interface occur at the shell-insert interface, and not at the bone-shell interface. This distinction is critical to the patients receiving this type of device: while both failures will require reoperation, the failure at the shell-insert interface would be a simpler procedure technically, and would require less operative time for the patient. However, if a well-seated, well-fixed acetabular shell separated from the bony acetabulum, the revision procedure would be much more extensive. Depending upon the clinical presentation, more extensive surgical reconstruction (including bone grafting) may be required. If the acetabulum cannot accommodate a shell that accepts a constrained liner, another procedure (hip fusion) with more devastating consequences to the patient may be required.

The concern cited is based upon the reduced range of motion achieved with these types of devices, and the resultant increased risk for femoral neck impingement on the constrained liner. If femoral neck impingement occurs, increased torque will be placed on the constrained liner-acetabular shell complex. If this torque is excessive, failure of the construct can be noted. A properly designed constrained liner would direct possible failure forces to either the femoral head-liner interface, or the insert-shell interface. In a recent case study on dislocation of a constrained acetabular component where recurrent dislocation was treated with a closed reduction, authors commented "perhaps component designers envisioned dislocation of the

femoral head through an intact ring rather than risk catastrophic failure of acetabular fixation."[1] This observation underscores the importance of understanding the potential failure modes for these types of devices. Clinical failures at the bone-shell interface, or the cement-shell interface have been noted in the medical literature.[2]

The notice of reclassification is legally and procedurally flawed, and would be difficult if not impossible to justify in response to a judicial challenge, because the Agency has failed to even consider the *specific* risks posed by shell-bone interface failures. *See* 66 Fed. Reg. 46563, 46565 (Sept. 6, 2001). Instead the notice recognized only *general* risks of infection, adverse tissue reaction, pain and/or loss of function, and revision caused by these three risk factors. Accordingly, the proposed special controls for this type of device fail to provide adequate assurance against the risk of shell-bone interface failures. Specifically, the special controls published by the Food and Drug Administration that are designed to control the risks associated with this type of device call for mechanical testing as a pre-clinical requirement. This type of special control is inadequate for this device. To adequately assess the safety and effectiveness of these devices, Premarket Approval Applications that contain clinical data must be required. Often, minor design variations that do not appear to be significant in bench testing have very significant clinical implications. New designs should be examined with the same scrutiny that current legally marketed devices have received. Clinical trials should be required for new designs to show that these devices are safe and effective, and to show clinically that the failure modes do not put the patient at greater risk of loss of function.

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1 Miller, CW and Zura, RD, Closed Reduction of a Dislocation of a Constrained Acetabular Component, Journal of Arthroplasty, Vol. 16 No. 4, 2001, pages 504-505.

2 Goetz, DD, Capello, WN, Callaghan, JJ, Brown, TD, and Johnston, RC, Salvage of a Recurrently Dislocating Total Hip Prosthesis with Use of a Constrained Acetabular Component, JBJS, Vol. 80-A, No. 4, April 1998, pages 502-509.

Because of the great risk to the intended patient population, and the limited effectiveness of bench testing in revealing a clinical failure mode, these devices should remain in Class III. These devices will then receive the scrutiny that they deserve, in order to provide adequate protection of the public health.

Respectfully submitted,

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