

SECTION XI
CONCLUSION

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Through this petition, OSMA requests the reclassification of metal/metal semi-constrained, cemented and uncemented total hip prostheses from class III into class II. In support of this request, long-term data from three separate regulated clinical studies performed in the U.S., one regulated multicenter study from Europe, a summary of the clinical results reported in the literature, and a summary of the testing of these devices from the published literature have been provided. The history of the use of these devices has defined the risks and potential adverse effects associated with metal/metal articulations. We believe this petition shows that these risks can be adequately controlled through FDA's established authority over class II devices.