

Product Classification



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Device	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer
Regulation Description	Ankle joint metal/polymer semi-constrained cemented prosthesis.
Regulation Medical Specialty	Orthopedic
Review Panel	Orthopedic
Product Code	HSN
Submission Type	510(k)
Regulation Number	888.3110
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Recognized Consensus Standards	

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[ASTM F 983-86 \(Reapproved 2009\) Standard Practice for Permanent Marking of Orthopaedic Implant Components](#)
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[ASTM F 565-04 \(Reapproved 2009\)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments](#)

Third Party Review Not Third Party Eligible

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