

K970394 OSTEONICS NORMALIZED AD-HA ACETABULAR COMPONENT SYSTEMApr 22, 1997
78 days to decisionK970394 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k970394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Feb 3, 1997
Decision date	Apr 22, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteonics Corp.
Location	Mchenry, IL, US
Contact	TERRY SHERIDAN
510(k) history	178 submissions · 136 cleared · 1980-2000

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