

K983382 OSTEONICS HA GENERATION II ACETABULAR COMPONENT SYSTEMDec 11, 1998
77 days to decisionK983382 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k983382/>**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	Sep 25, 1998
Decision date	Dec 11, 1998
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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