

K912654 OMNIFIT EPF DUAL GEOMETRY ACETABULAR CUPAug 16, 1991
60 days to decisionK912654 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k912654/>**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	Jun 17, 1991
Decision date	Aug 16, 1991
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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