

K884398 OMNIFIT TOTAL KNEE SERIES II TIBIAL INSERTSJan 17, 1989
90 days to decisionK884398 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k884398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 19, 1988
Decision date	Jan 17, 1989
Days to decision	90 days
Third-party review	No

APPLICANT

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

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