FDA 510(k) Premarket Notification

CLEARED

K973406 OSTEONICS SERIES 7000 TOTAL KNEE AUGMENTED FEMORAL COMPONENT

Dec 8, 1997
90 days to decision

K973406 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k973406/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 9, 1997
Decision date	Dec 8, 1997
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Osteonics Corp.**
Location	Mchenry, IL, US
Contact	DONNA S WILSON
510(k) history	178 submissions · 136 cleared · 1980-2000