FDA 510(k) Premarket Notification

K844355 SYNATOMIC STANDARD TIBIAL PLATEAU

CLEARED

Feb 7, 1985
90 days to decision

K844355 · Product code: **HSX** · Orthopedic
Source: https://www.510kdatabase.net/k844355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Nov 9, 1984
Decision date	Feb 7, 1985
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Depuy, Inc.**
Location	Mchenry, IL, US
Contact	JUDITH DERMODY
510(k) history	303 submissions · 239 cleared · 1976-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k844355/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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