FDA 510(k) Premarket Notification

K810328 BIO CONDYLAR TM KNEE

CLEARED

Apr 8, 1981
58 days to decision

K810328 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k810328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 9, 1981
Decision date	Apr 8, 1981
Days to decision	58 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k810328/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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