FDA 510(k) Premarket Notification

K915512 DURACON TOTAL KNEE SYSTEM TIBIAL COMPONENTS

CLEARED

Aug 18, 1992
253 days to decision

K915512 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k915512/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 9, 1991
Decision date	Aug 18, 1992
Days to decision	253 days
Third-party review	No

APPLICANT

Company	**Pfizer Hospital Products Group, Inc.**
Location	Fall River, MA, US
Contact	MARGARET CROWE
510(k) history	8 submissions · 7 cleared · 1991-1994