FDA 510(k) Premarket Notification

K954138 DURACON MONOLITHIC STABILIZER FEMORAL COMPONENT

CLEARED

Nov 21, 1995
81 days to decision

K954138 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k954138/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 1, 1995
Decision date	Nov 21, 1995
Days to decision	81 days
Third-party review	No

APPLICANT

Company	**Howmedica Corp.**
Location	Mchenry, IL, US
510(k) history	373 submissions · 325 cleared · 1976-1998