FDA 510(k) Premarket Notification

K910483 MONOTUBE EXTERNAL FIXATION SYSTEM

CLEARED

Jul 14, 1992
524 days to decision

K910483 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k910483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Feb 6, 1991
Decision date	Jul 14, 1992
Days to decision	524 days
Third-party review	No

APPLICANT

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