FDA 510(k) Premarket Notification

K915889 MITEK BONE ANCHOR, MODIFICATION

CLEARED

Oct 22, 1992
307 days to decision

K915889 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k915889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Dec 20, 1991
Decision date	Oct 22, 1992
Days to decision	307 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mitek Surgical Products, Inc.**
Location	Dedham, MA, US
Contact	EDWARD F KENT
510(k) history	31 submissions · 26 cleared · 1989-1996