FDA 510(k) Premarket Notification

K970423 INNOVASIVE ROCLET BONE TUNNEL AUGMENTATION DEVICE

CLEARED

Apr 30, 1997
85 days to decision

K970423 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k970423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Feb 4, 1997
Decision date	Apr 30, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovasive Devices, Inc.**
Location	Hopkinton, MA, US
Contact	ERIC BANNON
510(k) history	34 submissions · 31 cleared · 1993-2000