

K970119 MITEK ABSORBABLE POLYDIOXANONE (PDS) H FIXJan 30, 1998
381 days to decisionK970119 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k970119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jan 14, 1997
Decision date	Jan 30, 1998
Days to decision	381 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mitek Products
Location	Westwood, MA, US
Contact	EDWARD F KENT
510(k) history	30 submissions · 30 cleared · 1996-2002

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