

**K981714 TIMX LOW BACK SYSTEM TITANIUM MX ROD BASED
LOW BACK SYSTEM**

Jun 30, 1998
46 days to decision

K981714 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k981714/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 15, 1998
Decision date	Jun 30, 1998
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acromed Corp.
Location	Cleveland, OH, US
Contact	MARY LEWIS
510(k) history	41 submissions · 22 cleared · 1984-1998

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Device record: <https://www.510kdatabase.net/k981714/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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