

**K982354 SD TRANS-OSSEOUS FASTENER MODELS TOB 6
BOLT 32/50, TOB 6 BOLT 50/80, TOB 6 BOLT 80/140, TOB 6
WASHER MODELS 12MM 16MM 1M**

Nov 23, 1998
140 days to decision

K982354 · Product code: HTN · Orthopedic
Source: <https://www.510kdatabase.net/k982354/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Jul 6, 1998
Decision date	Nov 23, 1998
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Special Devices, Inc.
Location	Grass Valley, CA, US
Contact	JOSEPH J SPRANZA
510(k) history	2 submissions · 2 cleared · 1998-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026